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# EUROPEAN CHEMICALS BUREAU NEWSLETTER

Reporting on the scientific and technical aspects of the work carried out and co-ordinated by the ECB in support of European legislation on chemicals control.

## In this issue

This issue of the ECB Newsletter summarises the latest developments of the work carried out and co-ordinated by the ECB in support of the European legislation on dangerous substances.

The section on **Existing Substances** reports on the progress made at the Technical Meeting on 16-19 September 2003. Updates on the **New Substances Meeting**, **Testing Methods** and on the work programme of the OECD *Ad Hoc* Expert Group on **(Q)SARs** are presented. An overview on the forthcoming **Meetings** and further news about the **ECB website** are also reported.

## Existing Substances

### General Reflection

#### Highlights from the 37<sup>th</sup> Technical Meeting (16-19 September 2003)

The Technical Meeting discussed issues relating to **23** substances including 7 new ones: 2-methoxy-2-methylbutane (environment & human health), 4-methyl-m-phenylenediamine (environment & human health), hexachlorocyclopentadiene (environment), trisodium nitrilotriacetate (environment), disodium tetraborate, boric acid and boric acid, crude natural (proposal for a targeted risk assessment, see page 5).

This edition of the Newsletter reports on the status of hexabromocyclododecane (environment & human health), hexachlorocyclopentadiene (environment), 2-furaldehyde (human health), phenol (human health), chloroform (environment), 2-methoxy-2-methylbutane (environment & human health), nickel and nickel compounds (environment & human health), trisodium nitrilotriacetate (environment), 4-methyl-m-phenylenediamine (environment & human health), zinc and zinc compounds (environment).

### Progress in 2003

Member State Rapporteurs have completed the first draft Risk Assessment Reports on **113** out of a total of 141 priority substances listed on the first four priority lists, since the ESR programme started in 1993. Of those 113 substances, 15 substances were assessed for the Environment part only and 1 substance for the Human Health part only. ([View the lists of priority substances on the ECB website](#)).

The scientific and technical discussions at the Technical Meetings have been finalised and the conclusions agreed for **65** of the 110 priority substances (see detailed list page 6), with additionally **6** substances finalised for the Environment and **7** for Human Health. The following general conclusions have been drawn for the 65 finalised substances:

- **52** substances need risk reduction measures (**conclusion (iii)**);

- Further information is necessary for **2** substances, before final conclusions can be reached (**conclusion (i)**);
- For **11** substances the risk assessment concludes that there is no need for further information and/or testing or for risk reduction measures beyond those which are already being applied (**conclusion (ii)**).

The results of the whole evaluation under Reg. 793/93 have been published for 17 substances, 12 of which needed further risk reduction.



EUROPEAN COMMISSION  
JOINT RESEARCH CENTRE

## Further News on ESR Risk Assessment Reports

The **European Union Risk Assessment Tracking System (EURATS)** provides information on the status of the discussions and the conclusions reached by the Technical Meeting on ESR Priority Substances. The substance-by-substance status report forms and overviews of the conclusions reached by the TM are available as pdf files from the ECB's existing substances internet site. The information is updated quarterly.

### Progress on Individual Priority Substances

#### Hexabromocyclododecane (Sweden)

##### Environment:

For the environmental part, chapter 1 (General Substance Information) is now agreed. Concerning classification, Industry might voluntarily perform a new algae study, meanwhile the proposed classification is agreed. For the exposure part some late information on textile scenarios will be included. Industry will deliver information on existing recycling systems for demolition of buildings. The recently performed simulation degradation study has been evaluated and it was concluded to request a new biodegradation simulation test that should provide "valid half-lives as well as identification of metabolites". Industry will send a draft protocol during the last week of September and Member States can comment on that draft until 31 October. After revision, based on the received comments, the draft protocol will be discussed and decided at TM IV'03. In parallel, the Rapporteur and Industry will come up with a document discussing the need for specific investigation of the  $\alpha$ - and  $\beta$ -isomers. The Rapporteur will revise PEC for sediment

and soil and consider possible need for further toxicity tests for these compartments. This will also be discussed at TM IV'03. The final discussion for the environmental part is expected when the new degradation data are available, at the latest at TM IV'04.

##### Human Health:

For the human health part the exposure and effects assessments are in principle agreed. New data have removed the concerns for sensitisation. There is concern for repeated dose toxicity in some occupational scenarios, but there is a continuing discussion on what margin of safety to aim at in the risk characterisation. There is no concern for consumers. There was no discussion for humans exposed via the environment. A developmental neurotoxicity study on hexabromocyclododecane will be discussed at TM I'04, and a final discussion of the full report is planned for when the environmental part will be discussed next, i.e., at the latest at TM IV'04. Data generated meanwhile will be included in the final risk assessment report.

CAS: 25637-99-4, EINECS: 247-148-4

#### 2-Furaldehyde (The Netherlands)

##### Human Health:

At TM III'03 the discussion focussed on the results of an *in vivo* gene mutation test showing that 2-furaldehyde is not an *in vivo* mutagen.

For carcinogenicity, cat 3 (R40) will be proposed and

risk characterisation will be based on a threshold approach.

As conclusions to all other end-points were already agreed upon before, the risk assessment report will soon be sent out for final written comments.

CAS: 98-01-1, EINECS: 202-627-7

#### Hexachlorocyclopentadiene (The Netherlands)

##### Environment:

Production of hexachlorocyclopentadiene (HCCP) is currently limited to only one company in the USA, while in Europe only two major applications of HCCP are relevant. HCCP is used as an intermediate in the production of endosulfan and in the synthesis of HET-acid. The latter is used as a copolymer to produce flame-retardant and corrosion-proof polyesters and alkyl resins. In the year 2000 import was between 2,000 and 6,000 tonnes HCCP. The first draft of the environmental risk assessment report (RAR) was sent out for written comments earlier in 2003. The current draft does not yet contain the environmental risk assessment for the wastewater treatment plant (awaiting results of an OECD 209 test) and secondary poisoning (awaiting completion of human health part).

A response-to-comments was provided prior to TM III'03 by

the Rapporteur and a brief discussion took place during TM III'03. Upon request of the Technical Meeting, the Rapporteur will provide more details in the following draft on some of the key studies. In general, however, the Technical Meeting approved the RAR. One statement that HCCP would occur in relatively high levels in whale blubber appeared to be a misunderstanding. In addition, the RAR concludes that HCCP itself is not a PBT, but it contains approximately 1% of a PBT, i.e. hexachlorobutadiene. The Technical Meeting asked the Rapporteur to come forward with a proposal on how to deal with that.

The last visit discussion on the revised report with the response to comments included is scheduled mid 2004.

CAS: 77-47-4, EINECS: 201-029-3

#### Explanation of conclusions

- (i) There is need for further information and/or testing.
- (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.
- (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

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*Progress on Individual Priority Substances continued from page 2***Phenol (Germany)****Human Health:**

The second in-depth discussion on the human health section of the revised risk assessment report on Phenol took place at TM III'03. The revision was done on the basis of the written comments provided by the Member States. The environmental sections were already finalised previously.

For phenol, three occupational exposure scenarios have been defined (production and further processing as a chemical intermediate, formulation and use of phenolic resins). It was decided to further add a dermal subscenario for spray coating using phenolic resins. Minor changes on the exposure assessments for consumers (household products and cosmetics) have to be performed. However, these are without influence on the risk characterisation for consumers (conclusion (iii)).

The TM agreed in general on the effects assessment for all endpoints except mutagenicity. The LOAEC for systemic effects following repeated inha-

lation is now based on changes of haematological and clinical parameters of occupationally exposed workers. The changed interpretation of the genotoxicity data due to recent information on an indirect mode of action via phenol-induced hypothermia needs further consideration.

Risk characterisation for workers recognises concern for both corrosivity of phenol and for its systemic effects following dermal and inhalation exposure. Because of the open questions on mutagenicity the conclusions for the endpoints mutagenicity and carcinogenicity are still open.

The dermal exposure via cosmetics in the risk characterisation for consumers (conclusion (iii)) needs to be discussed again. The risk characterisation for humans exposed via the environment was tentatively agreed.

The next discussion on the human health risk assessment is foreseen to take place at TM I'04 on the basis of a revised draft report.

*CAS: 108-95-2, EINECS: 203-632-7*

**2-Methoxy-2-methylbutane (Finland)****Environment:**

The first in-depth discussion of the environmental risk assessment report of the petrol additive 2-methoxy-2-methylbutane (TAME) took place at TMIII'03. The Rapporteur informed the TM about chronic aquatic tests industry was volunteered to carry out to confirm the aquatic PNEC and environmental classification. In addition, the possible fish avoidance behaviour will be considered after the result of the test with MTBE will be available.

The similarity of TAME and MTBE regarding taste and odour characteristics were discussed at the TM and the Rapporteur agreed to consider the points raised. Thus, no further testing was recommended. The TM agreed the preliminary conclusion (iii)

regarding identified local risks in petrol delivery and storage at terminal sites and intermittent releases from storage tank bottom waters. In addition, conclusion (iii) applies to overall quality of groundwater. This conclusion (iii) is not based on ecotoxicological endpoints but it is reached because of taste and odour and overall quality of groundwater as a consequence of exposure arising from leaking underground storage tanks, tank piping and spillage from overflowing the tanks. Some of the Member States requested additional groundwater monitoring data to better describe the character and extent of this risk.

The preliminary time schedule regarding last visit discussion and finalisation of the risk assessment was set to TM I'04.

**Chloroform (France)****Environment:**

Based on the discussions at TM III'02 and written comments, the risk assessment report was revised and distributed in August 2003. The main changes concern the exposure part: emission rates were modified for some scenarios (uses for dyes and pesticides production, uses as a solvent), for the releases as a by-product due to the manufacture of other chlorinated chemicals and for some production sites where default values had to be used. The TM agreed with these modifications.

A conclusion (ii) is derived for the aquatic compartment, except for the uses as a solvent (conclusion (iii)). For the sediment compartment and for sewage treatment processes, conclusions (i) already agreed

at TM III'02 for several production sites and for all uses are still valid. Therefore, the following information/testing requirements will be published in the second regulation under article 10 (2) of regulation 793/93: environmental exposure information for production and uses, two long-term toxicity tests on benthic organisms and toxicity tests on micro-organisms (nitrification inhibition tests and inhibition of methanogenic bacteria).

The draft will be revised with updated information from Industry and Italy on import, export and HCFC 22 production volumes and in view of the additional experimental and exposure data requested. A last visit discussion is expected at TM III'04.

*CAS: 67-66-3, EINECS: 200-663-8*

**Human Health:**

The first in-depth discussion on the human health sections of the risk assessment also took place at TM III'03.

The TM generally agreed on the worker exposure assessment. Industry supported the idea to perform worker exposure measurements for the petrol pump repair scenario. The sections on consumer exposure and humans exposed via the environment were agreed apart from some further clarification of the odour and taste threshold.

In the effects assessment, repeated dose toxicity, mutagenicity and carcinogenicity sections will need some additional data and refinement of details. Reproductive toxicity will need further

consideration by the participants before agreement can be made. Issues were left open in the 2-generation fertility study and the meeting did not express a final opinion on the relevance of the findings in the developmental toxicity study in mice.

The risk characterisation was not discussed in-depth because of the outstanding clarifications required in the hazard assessment and the definition of minimal MOS.

The Rapporteur would table a revised human health report for TM I'04 at the earliest.

*CAS: 994-05-8, EINECS: 213-611-4*

*Continued on page 4*

*Progress on Individual Priority Substances continued from page 3*

## Nickel and nickel compounds (Denmark)

### Environment:

An update of the environmental effect assessment on metallic nickel and the four other priority nickel compounds were briefly presented as scheduled at TM III'03. The revision of the draft had been made taking into account the comments on the previous draft from Member States and Industry. The revised draft included improved explanations regarding speciation of the nickel ion in water and possible consequences for the availability of nickel, a preliminary marine effect assessment and a provisional PBT assessment. For the terrestrial part, a further analysis was provided and substantiation had been made of the reasons why pooling of data on plants and soil dwelling organisms does not seem to be justified. The Rapporteur had also revised the environmental (aquatic) hazard classification proposal based on available data. The Rapporteur explained the most critical issues in this regard based on his response to some comments made by Industry on a previous draft proposal

which were submitted to the C&L meeting (environment) in June, but not discussed at that meeting. The TM also did not discuss this or any of the other mentioned issues, because the TM including Industry felt that a postponement of such discussions were more appropriate. It was agreed that a formal conclusion should be drawn regarding the need for further ecotoxicological research on nickel, including deadlines for completion of this work. Such work actually is already in progress sponsored by Industry. The status and the objectives of this work especially regarding the bioavailability issues were presented to participants from Member States at a workshop arranged by Industry the day before the TM. The Rapporteur intends in the forthcoming time period to concentrate on revising a draft environmental exposure assessment, which has recently been submitted by Industry. This revision process will take place in close corporation with Industry. Presently it is assumed that the first draft environmental exposure assess-

ment will be circulated for comments early next year and a revised version probably be discussed at TM II'04.

### Human Health:

The TM discussed the five prioritised nickel substances (metal, sulphate, carbonate, chloride and nitrate).

The occupational exposure estimates were provisionally agreed at TM II'03 pending a further refinement of the data by Industry within a period of two months. The sections on consumer exposure (only relevant for nickel metal and nickel sulphate) were agreed.

Most of the effect assessments were already agreed at TM II'03. The further changes relating to acute toxicity, repeated dose toxicity and sensitisation were all agreed.

The Rapporteur proposals to classify the four nickel salts as Carc. Cat. 1; R49 and nickel metal as Carc. Cat. 3 were accepted to be forwarded to the C&L CMR working group. The TM suggested to consult on

that matter the Specialised Experts Group, which discussed this issue already in 1997.

The issue of further testing for mutagenicity will be discussed by the *ad hoc* steering group.

Agreement was also reached on major parts of the risk characterisation including the conclusions of all five reports, though transparency in the evaluation of the Margins of Safety has to be improved. The Rapporteur will reword the sections on particle size distribution and the possible relevance to the human exposure estimates. With respect to nickel carbonate and nickel nitrate the request for further data regarding local effects, conclusion (i) was approved.

The Rapporteur will submit revised draft reports for discussion at TM II'04.

CAS: 7440-02-0, EINECS: 231-111-4  
CAS: 7786-81-4, EINECS: 232-104-9  
CAS: 3333-67-3, EINECS: 222-068-2  
CAS: 7718-54-9, EINECS: 231-743-0  
CAS: 13138-45-9, EINECS: 236-068-5

## Trisodium nitrilotriacetate (Germany)

### Environment:

The first in-depth discussion on the environmental part of the risk assessment of trisodium nitrilotriacetate (NTA) took place at TM III'03. Agreement on all issues was reached. Therefore, the assessment will be finalised by written procedure.

Main points of the risk assessment are:

- NTA is used as complexing agent in textile cleaning, in both household and industrial applications. In addition to this, it is used in cleaning agents for industrial applications, especially in neutral and alkaline liquid cleaners.
- Ecotoxicological effects of NTA are related to the complexation of metals causing disturbance of the metal metabolism. Results from stan-

dard tests for algae toxicity were unsuitable for risk assessment purposes because of the complexation of essential metals in the test medium leading to nutrient deficiency.

- Uncomplexed NTA is readily biodegradable, but it was demonstrated that biodegradation is influenced by the metal speciation. Since in both sewage and the hydrosphere a mixture of complexes is always present, a prediction of the degradation rates from laboratory tests is not possible. Based on measurements, elimination in treatment plants of 95% and a half-life for surface water of 5 days is used in the risk assessment.

The environmental risk assessment results in a conclusion (ii) for all compartments.

CAS: 5064-31-3, EINECS: 225-768-6

## Targeted risk assessments and Strategic Partnerships

Austria presented a proposal on how to cope with the two priority substances boric acid and disodium tetraborate having in view the forthcoming REACH system: targeting the risk assessment for these priority substances as well as establishing a strategic partnership with Industry.

The ECB and the Member States welcomed the Austrian proposal, in particular to speed up the procedure for the 4<sup>th</sup> priority list substances in the Existing Substances Programme. However, the ECB saw a need to discuss political aspects of strategic partnerships within the European Commission. Comments on

the presented proposal were received from D, S, DK, UK, NL, concerning the choice of uses that will be assessed or that were excluded from the targeted assessment; protection goals/organisms that will be covered by the environmental effect assessment; the tasks and responsibilities of the rapporteur and industry as well as the format of the report. The Austrian Rapporteur will revise the discussion documents and present its proposal at the Competent Authorities meeting in November.

CAS: 1330-43-4, EINECS: 215-540-4  
CAS: 11113-50-1, EINECS: 234-343-4  
CAS: 10043-35-3, EINECS: 233-139-2

*Continued on page 5*

*Progress on Individual Priority Substances continued from page 4*

#### 4-Methyl-m-phenylenediamine (Germany)

The risk assessment report for 4-methyl-m-phenylenediamine (TDA) was tabled for an in-depth discussion at the TM III'03.

##### **Environment:**

For the environmental assessment the main discussion points were the derivation of the  $PNEC_{\text{aqua}}$  based on short-term effect values for a very sensitive fish species that were lower than NOECs from available long-term tests and the derivation of the  $PNEC_{\text{sediment}}$  on the basis of the  $PNEC_{\text{aqua}}$  via the equilibrium partitioning method (EPM).

Concerning the  $PNEC_{\text{aqua}}$ , Industry questioned both the relevance and the validity of the lowest short-term effect value obtained with a fish species that is native to South-Pacific coastal waters. The TM reached agreement that the  $PNEC_{\text{aqua}}$  should be based on this value, if the validity of the

test can be shown (oxygen content of the test solution).

Concerning the  $PNEC_{\text{sediment}}$  no agreement was reached whether an additional factor of 10 should be applied on the value derived via the EPM to consider uptake of sediment-bound substance via ingestion. The request for sediment tests with benthic organisms depends on the application of this additional factor.

The Rapporteur was invited to check the validity of the fish test and to check once more the arguments for the additional factor of 10 and thus the need for sediment tests.

##### **Human Health:**

The revision of the risk assessment report was done on the basis of the written comments provided by the Member States.

The exposure assessment for workers is still under discussion and revision. Industry provided

further information that inhalation and dermal exposure during production and further processing of TDA is very low. It was proposed to add a further scenario for the use of TDA in the production of dyes. There is no information available about direct use of TDA in consumer products. Additionally, the possibility of a liberation of TDA from polyurethane products should be examined.

The TM agreed in general on the effects assessment except for toxicokinetics. The estimation of the extent of absorption for oral uptake has to be verified because of possible consequences for the risk characterization under repeated dose toxicity. Hazard assessment for developmental toxicity cannot be completed because of the lack of valid data. Occupational risk assessment especially concentrates on the diffi-

cult issue, whether "very low exposure" to TDA during its production and processing directly means "very low carcinogenic risk". Based on a distinct description of occupational exposure the remaining carcinogenic risks have to be transparently characterised in order to allow for a sound risk evaluation. The risk characterisation for humans exposed via the environment was tentatively agreed because of minor alterations resulting from recalculation of the exposure data. However, a change of the conclusion (iii) is not expected because the substance is considered as a genotoxic carcinogen.

The next visit discussion on human health risk assessment of TDA is expected to take place at TM I'04 on the basis of a revised risk assessment report.

CAS: 95-80-7, EINECS: 202-453-1

#### Zinc and zinc compounds (The Netherlands)

##### **Environment:**

At TM III'03 the assessment factors that were used to derive the PNECs for water and sediment of zinc were rediscussed, since there appeared to be some questions around it. The great majority of the Member States, however, expressed their support for these assessment factors and also for the PNECs for water and sediment, further substantiated by scientific arguments, consequently the PNECs for water and sediment were adopted.

After an initial written commenting round, the PNEC of zinc for soft water was also discussed at TM III'03. Agreement was reached upon the value of 3.1 µg/L (as added and dissolved value) as well as where this PNEC soft water should be applied to, i.e. to waters with a hardness level of between 5 and 24 mg/L as CaCO<sub>3</sub>.

The discussions on how bioavailability of zinc in water, sediment and soil could be integrated in the risk assessment report were continued following

TM II'03. For water, agreement was reached on the method that takes into account the site-specific or region-specific bioavailability correction for the PECs. An essential element of this correction is using Biotic Ligand Models (BLMs) for algae, Daphnia and fish, that take into account the speciation of zinc in the water, the competition of various cations in the water towards the organisms, and the chronic toxicity of zinc to the organisms. The outcome of the BLM bioavailability correction, depends on the selection of the input parameters, such as the exact value of the concentration of Dissolved Organic Carbon (DOC) in the water.

For sediment, the approach taking into account Acid Volatile Sulphide (AVS), i.e. sequestration of zinc by sulphides in the anaerobic sediment layers, as a correction for bioavailability of zinc in the sediment, was adopted by the TM. Only for those sites and regions where information on

AVS is available, AVS-correction would be applied. A proposal from Industry to use a generic bioavailability factor that is based on a Flemish database needs further exploration before it can be agreed on. Both for water and for sediment, the TM agreed with the proposal by the Rapporteur to show various scenarios in the risk characterisation (sensitivity analysis). A series of input parameters will be taken, ranging from over-conservative to more realistic worst-case.

For soil, the Rapporteur did not agree with the regressions proposed by Industry to correct for bioavailability of zinc in soil. The main reason was that the Rapporteur concluded that these regressions had poor statistics and poor predictive power. The Rapporteur on the other hand proposed using one single PNEC for all soils in combination with a lab-to-field bioavailability correction factor. The latter factor is mainly to account for ageing effects, i.e. the recognition that when

zinc is present in the soil for a long time, the toxicity becomes less pronounced. Since in the current risk assessment report only some soils are at risk, in particularly those that receive zinc over many years, a lab-to-field bioavailability correction factor of 3 was justified and adopted by the TM. However, in some other cases, zinc may receive higher concentrations in the soil over relatively short time, where a lab-to-field bioavailability correction factor of 2 was considered more appropriate.

The TM finally agreed that Industry would be given some more time to show the uncertainty of their proposed regressions and how this uncertainty would propagate into the risk characterisation for the soil compartment.

CAS: 7440-66-6, EINECS: 231-175-3  
CAS: 1314-13-2, EINECS: 215-222-5  
CAS: 557-05-1, EINECS: 209-151-9  
CAS: 7646-85-7, EINECS: 231-592-0  
CAS: 7733-02-0, EINECS: 231-793-3  
CAS: 7799-90-0, EINECS: 231-944-3

## Substances for which the ESR Technical Meeting has agreed on the risk assessment

CAS Number	EINECS Name		CAS Number	EINECS Name		CAS Number	EINECS Name	
<b>1<sup>st</sup> Priority list</b>								
60-00-4	edetic acid	D	84-74-2	dibutyl phthalate	NL	110-65-6	but-2-yne-1,4-diol	D
62-53-3	aniline	D	91-20-3	naphthalene	UK	110-82-7	cyclohexane	F
64-02-8	tetrasodium ethylene diaminetetraacetate	D	95-76-1	3,4-dichloroaniline	D	111-77-3	2-(2-methoxyethoxy) ethanol	NL
71-43-2	benzene	D	98-82-8	cumene	E	112-34-5	2-(2-butoxyethoxy) ethanol	NL
75-05-8	acetonitrile	E	101-77-9	4,4'-methylenedianiline	D	141-97-9	ethyl acetoacetate	D
79-01-6	trichloroethylene	UK	103-11-7	2-ethylhexyl acrylate	D	1163-19-5	bis(pentabromophenyl) ether	F/UK
79-06-1	acrylamide	UK	106-46-7	1,4-dichlorobenzene	F	1570-64-5	4-chloro-2-methyl phenol	DK
79-10-7	acrylic acid	D	106-99-0	1,3-butadiene	UK	7664-39-3	hydrogen fluoride	NL
79-20-9	methyl acetate	D	107-02-8	acrylaldehyde	NL	32536-52-0	diphenyl ether octabromo der.	F/UK
79-41-4	methacrylic acid	D	107-13-1	acrylonitrile	IRL	67774-74-7	benzene, C10-13-alkyl derivs.	I
80-62-6	methyl methacrylate	D	107-64-2	dimethyldioctadecyl ammonium chloride	D	85535-84-8	alkanes, C10-13, chloro-	UK
<b>2<sup>nd</sup> Priority list</b>								
75-56-9	methyloxirane	UK	117-81-7	bis(2-ethylhexyl) phthalate	S	28553-12-0	di-"isononyl" phthalate	F
77-78-1	dimethyl sulphate	NL	120-82-1	1,2,4-trichlorobenzene	DK	32534-81-9	diphenyl ether, pentabromo deriv.	UK
88-12-0	1-vinyl-2-pyrrolidone	UK	123-91-1	1,4-dioxane	NL	68515-48-0	1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich	F
90-04-0	o-anisidine	A	7722-84-1	hydrogen peroxide	FIN	68515-49-1	1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich	F
108-88-3	toluene	DK	25154-52-3	nonylphenol	UK	84852-15-3	phenol, 4-nonyl-, branched	UK
109-66-0	pentane	N	26761-40-0	di-"isodecyl" phthalate	F			
<b>3<sup>rd</sup> Priority list</b>								
79-11-8	chloroacetic acid	NL	110-85-0	piperazine	S	7775-11-3	sodium chromate	UK
80-05-7	bisphenol-A	UK	1306-19-0	cadmium oxide	B	7778-50-9	potassium dichromate	UK
81-14-1	4'-tert-butyl-2',6'-dimethyl-3',5'-dinitroacetophenone	NL	1333-82-0	chromium trioxide	UK	7789-09-5	ammonium dichromate	UK
81-15-2	5-tert-butyl-2,4,6-trinitro-m-xylene	NL	1634-04-4	tert-butyl methyl ether	FIN	10588-01-9	sodium dichromate	UK
85-68-7	benzyl butyl phthalate	N	7440-43-9	cadmium	B	26447-40-5	methylenediphenyl diiso cyanate	B

## Note:

CAS Chemical Abstracts Service  
 EINECS European Inventory of Existing Commercial Chemical Substances  
 ESR Existing Substance Regulation

## New publications

### Final versions of Risk Assessment Reports and Summaries added to the website:



- vol 16, diphenyl ether, octabromo derivative (CAS 32536-52-0)
- vol 30, toluene (CAS 108-88-3)
- vol 33, naphthalene (CAS 91-20-3)
- vol 34, methyl acetate (CAS 79-20-9)
- vol 35, 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (CAS 68515-48-0) & di-"isononyl" phthalate (DINP) (CAS 28553-12-0)
- vol 36, 1,2-Benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich (CAS 68515-49-1) & di-"isodecyl" phthalate (DIDP), (CAS 26761-40-0)

Also included: the summary report of bis(pentabromophenyl) ether.

### Draft Risk Assessment Reports added to website:

- monochloroacetic acid (CAS 79-11-8)
- musk xylene (CAS 81-15-2) & musk ketone (CAS 81-14-1)
- cadmium oxide (CAS 1306-19-0) & cadmium metal (CAS 7440-43-9)
- methylenediphenyl diisocyanate (CAS 26447-40-5)
- 2-ethylhexyl acrylate (CAS 103-11-7)

## ECB website

### Design and features:

- **ECB site map:** this updated version offers a visual representation of the site. From the map, the user can either move directly to a particular subject or view the complete table of contents.
- **ECB search engine:** the search engine was updated to facilitate the retrieval of pages or files within the ECB site. Information can be searched by keyword. The page of results provides the titles of documents related to the topic of interest with a short description, as well as a direct access to the selected documents.

These enhanced features are based on the latest release of the server-side scripting solution PHP 4.3. They are available on the ECB home page.

### ESIS (European chemical Substances Information System):

- A new module, [IUCLID D.S], was implemented into ESIS. It provides information exported from the IUCLID database on High Production Volume Chemicals (HPVC) reported by the European industry. The 2605 chemical reports available can be accessed from a list classified by CAS or EINECS numbers.
- It is now also possible from any list of ESIS (HPVCs, LPVCs, Priority Lists, etc.) by selecting a CAS or EINECS number to access all information available for a particular substance (general information, classification and labelling, IUCLID data sheet, risk assessment information, etc.).
- The module on Regulation Results, [REG. RES.], was moved and merged with the module on Risk Assessment Tracking System [ORATS].

## New Substances

### 17<sup>th</sup> Technical & Scientific Meeting

9<sup>th</sup>-10<sup>th</sup> September: New Substances work area of ECB held its **17<sup>th</sup> Technical & Scientific Meeting** at JRC Ispra. This six-monthly meeting was arranged as two sessions, separating confidential and non-confidential issues, to accommodate respective participation of member state representatives only and plenary participation of member state and accession country representatives together.

A principal ongoing issue relates to risk management of substances distributed through the EU market among multiple low volume notifications, but with significant cumulative total tonnages. Risk assessment of individual high production volume chemicals and

implementation of risk reduction measures for substances of concern also remain ongoing for follow up administration among regulatory authorities and Commission services.

The meeting considered notification queries relating both to individual cases (e.g., substance compositions) and procedural requirements (e.g., implementation of reduced testing programme for intermediates according to 28<sup>th</sup> ATP).

Also relevant to the New Substances forum is strategic planning for accession countries joining the notification scheme in 2004, coupled to longer term implementation of a new legislative framework (REACH) for industrial chemicals.

### Collaboration with ECVAM

Collaboration between ECB and ECVAM (European Centre for the Validation of Alternative Methods) continues. In particular, development of an *in vitro* skin irritation assay, relating to R38 classification, aims to replace *in vivo* studies. The new chemicals database at ECB provides a reference archive of high quality *in vivo* data and indicator of sub-

stances with potential for selection as samples appropriate to the validation study. Short-lists of candidate substances, subdivided as irritants and non-irritants, also differentiating EU and GHS classification definitions, are available. The project now seeks cooperation among identified suppliers to contribute specific chemicals for inter-laboratory testing.

### Manual of Decisions

The manual of decisions for implementation of the sixth and seventh amendments to Directive 67/548/EEC on Dangerous Substances (Directives 79/831/EEC and 92/32/EEC)

was updated. The publication is available on the ECB website:

<http://ecb.jrc.it/new-chemicals/>  
Non-confidential version.  
Publication: EUR 20519 EN.

## Forthcoming ECB meetings

7-8 October 2003	Biocides Technical Meeting	JRC, Ispra (IT)
27-28 October 2003	PBT Subgroup (3 <sup>rd</sup> meeting of the working group on the identification of PBT and vPvB substances)	Hotel Concorde, Arona (IT)
5-7 November 2003	Classification & Labelling of Dangerous Substances (working group on Environmental Effects)	JRC, Ispra (IT)
11-13 November 2003	TGD Revision Subgroup Meeting (Risk Characterisation for Human Health Treshold and Non-Threshold)	JRC, Ispra (IT)
11-14 November 2003	SIAM 17 (OECD) (17 <sup>th</sup> SIDS Initial Assessing Meeting of the chemical committee and	Hotel Concorde, Arona (IT)
13-14 November 2003	Classification & Labelling of New Substances: (working group on Environmental Effects, Member States only)	Roma (IT)
17-19 November 2003	Classification & Labelling of Dangerous Substances (working group on Health Effects, CMR substances)	JRC, Ispra (IT)
2-5 December 2003	38 <sup>th</sup> Technical Meeting on Existing Substances	Hotel Concorde, Arona (IT)

## (Q)SARs

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### OECD work programme

The JRC is coordinating Work Item 1 of the OECD work programme on (Q)SARs, which was described in the June newsletter. In this work item, the so-called "Setubal principles", proposed for the assessment of the scientific validity of (Q)SARs, are being evaluated. At present, the following models/programmes are included in the evaluation exercise:

- 1) QSARs for acute fish toxicity
- 2) a QSAR package for bio degradation (BIOWIN);
- 3) QSARs for mutagenicity and carcinogenicity;
- 4) SARs for one or more clinical endpoints;
- 5) a Multi-CASE model for *in vitro* chromosomal aberrations
- 6) QSARs for atmospheric degradation;
- 7) a QSAR for biodegradation developed by METI (Japanese Ministry of Economy, Trade and Industry).

In addition, a range of commercially-available software models for physico-chemical, human health and ecotoxicological effects, previously evaluated in ECETOC Techni-

cal Report No. 89, are being used by the ECETOC QSAR Task Force to assess the proposed Setubal principles.

It is foreseen that a draft report on the outcome of this exercise will be available by March 2004.

On 8 September, a meeting was held between the European Commission, the OECD Secretariat and representatives of global industry, to discuss the commitments of the different parties to the OECD work programme. All parties reiterated their commitment to the OECD activity, with the industry representatives requesting that a detailed business plan be prepared on completion of Work Item 1, to facilitate the consideration of how resources could be allocated to specific projects. The idea of establishing an international programme for validating QSARs, first raised by the Commission at the June Joint Meeting, was discussed, and it was suggested that such a programme could be initiated and run in parallel with Work Item 2 (development of technical guidance on QSARs).

### (Q)SAR website

General information on the JRC Activity on QSARs is now available at the following

website:  
<http://ecb.jrc.it/QSAR/>

### Publications

The proceedings of the workshop organised by the European Chemical Industry Council (CEFIC) and the International Council of Chemical Associations (ICCA) on the "Regulatory Acceptance of QSARs for Human Health and Environment Endpoints", held in Setubal, Portugal, in March 2002, were published in August (1-4).

(1) Jaworska, J.S., Comber, M., Auer, C. & Van Leeuwen, C.J. (2003). Summary of a workshop on regulatory acceptance of (Q)SARs for human health and environmental endpoints. *Environmental Health Perspectives* **111**, 1358-1360.

(2) Eriksson, L., Jaworska, J.S., Worth, A.P., Cronin, M.T.D., McDowell, R.M. & Gramatica, P. (2003). Methods for reliability and uncertainty assessment

and for applicability evaluations of classification- and regression-based QSARs. *Environmental Health Perspectives* **111**, 1361-1375.

(3) Cronin, M.T.D., Walker, J.D., Jaworska, J.S., Comber, M.H.I., Watts, C.D. & Worth, A.P. (2003). Use of quantitative structure-activity relationships in international decision-making frameworks to predict ecologic effects and environmental fate of chemical substances. *Environmental Health Perspectives* **111**, 1376-1390.

(4) Cronin, M.T.D., Jaworska, J.S., Walker, J.D., Comber, M.H.I., Watts, C.D. & Worth, A.P. (2003). Use of quantitative structure-activity relationships in international decision-making frameworks to predict health effects of chemical substances. *Environmental Health Perspectives* **111**, 1391-1401.

## Testing Methods

### Website updated!

The Testing Methods section of the ECB website was updated with, among other things:

- the lists of foreseen methods to be included in Annex V;
- a guidance document on granulometry;
- a draft method to determine

the LWGMD of synthetic vitreous fibres.

<http://ecb.jrc.it/testing-methods/>

## About the ECB Newsletter

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The ECB Newsletter gives topical information on the progress made relating to the scientific and technical work carried out in support of Council Directive 67/548/EEC (Test Methods, New Substances and Classification and Labelling), Council Regulation (EEC) No. 2455/92 (Import/Export), Council Regulation (EEC) No. 793/93 (Existing Substances) and Council and Parliament Directive 98/8/EC (Biocides). Activities under these regulations and directives are progressed via Technical Meetings of EU Member States, Commission and Non Governmental Organisations coordinated by ECB.

The Newsletter aims to inform policymakers and other persons working in adjoining fields of chemical management of the progress made by the Technical Meetings. There are four electronic publications a year.

The Newsletter and further information relating to the scientific and technical aspects of the work under Directives and Regulations are available from the ECB Internet site: <http://ecb.jrc.it>

### ECB Newsletter

*Produced by:*

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## About the ECB

The European Chemicals Bureau (ECB) provides scientific and technical support for the conception, development, implementation and monitoring of EU policies related to dangerous chemicals. The ECB is the focal point for collecting information on new and existing chemicals. It co-ordinates the EU risk assessment programmes covering the risks posed by existing and new substances to the humans and the environment. It supports the legal classification and labelling, the notification of new substances, the information exchange on import and export of dangerous substances, the development and harmonisation of testing methods and QSAR models, and the authorisation of biocides.

The ECB website provides more information on the ECB and in particular on:

- Standardised *Testing Methods* for the assessment of the hazardous properties of chemicals.
- The Technical Guidance Document on Risk Assessment (TGD), the risk assessment methodology for *Existing Substances*, *New Substances*, and *Biocides*.
- International Uniform Chemical Information Database (IUCLID), the database system used for *Existing Substances* and *Biocides*. Also selected by the *OECD Existing Substances* programme and the *ICCA*.
- European Union System for Evaluation of Substances (EUSES), the risk assessment tool used for *Existing Substances* and *New Chemicals*.
- Published Risk Assessment Reports for Priority *Existing Substances*.
- The Technical Notes for Guidance for *Biocides*.
- The review programme for existing active *Biocides*.
- The IUCLID Data Availability Study for *Existing Substances*.
- EUSES - IUCLID Training Courses.
- Proposals on Classification and Labelling for the upcoming ATP.

