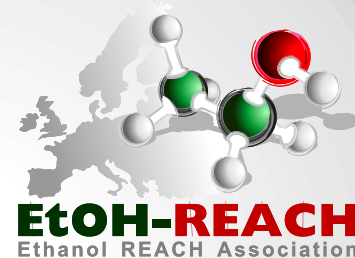




Welcome to the EtOH-REACH General Assembly 2013

Agenda



1) Introduction and Antitrust Law

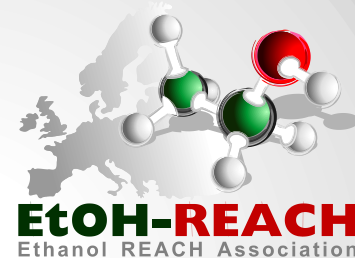
2) Ethanol

- Denaturants
- Classification and Labelling
- Ethanol Activities during 2013

3) Associated substances

4) Update to Fees regulation

Agenda (2)



5) Financial Reporting

6) Election of officials

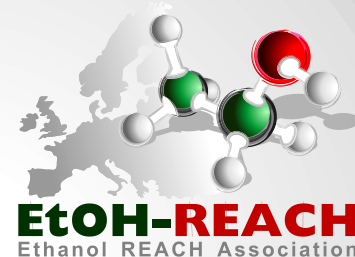
7) The future of EtOH-REACH

8) Questions before & closing the meeting



Denatured ethanol exposure scenarios

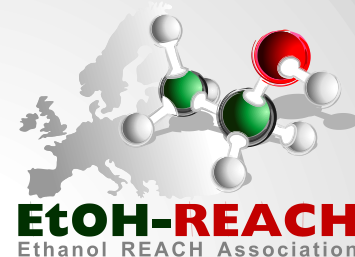
Denatured ethanol – coverage in REACH



- Mixture or preparation, so formulator is DU.
- Are denaturants registered?
 - Maybe, but no evidence use as a denaturant is specified
- Does standard ethanol ES cover denatured ethanol?
- New exposure scenarios may be required if not.

Note: Briefing note sent to members July 2011 explaining options available.
Update to be issued imminently

Denatured ethanol project



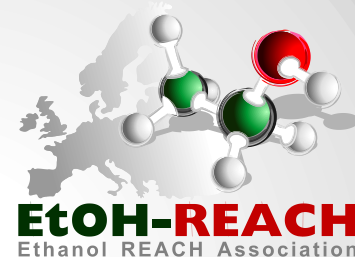
- Project split into four tasks:
- Task 1: Identify denaturants used by members (survey Spring 2012)
 - 121 identified as used in past 5 years, including dyes
 - 24 used by 3 or more members in past year. Taken forward to task 2.
- Task 2: Identify for these 24, the maximum percentage that could be used with the existing exposure scenarios (ethanol remaining as the critical component determining the RCR.)
 - Results circulated to members in August 2012
 - Members requested to identify those denaturants where the determined threshold was insufficient.

Maximum permissible with current EtOH ES

Denaturant	Maximum
Isopropanol (IPA)	28%
t-butanol	10%
Methylene blue	10%
n-propanol	8.25%
Acetone	6.40%
n-butanol	3.6%
Ethyl acetate	3.54%
Toluene	3.24%
Isobutanol	1.72%
Isopropyl acetate	1.67%
Methyl ethyl ketone (MEK)	1.62%
Methanol	1.45%

Denaturant	Maximum
Menthol	1.33%
Bitrex	1%
Methyl tertiary butyl ether (MTBE)	0.74%
Ethyl t-butyl ether (ETBE)	0.56%
Cyclohexane	0.54%
Methyl isobutyl ketone (MIBK)	0.13%
n-hexane	0.11%
Wood naphtha	0.01%
Methyl isopropyl ketone (MIPK)	0.01%
Linalool	0.0041%
Diethyl phthalate	0.0022%

Denatured ethanol project

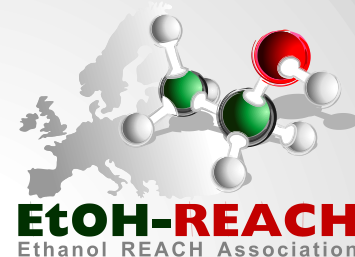


- Task 3a: Members resurveyed and asked if these were sufficient and, if not, what levels are used and in which uses:
 - Results:

Uses	Gasoline [‡] , MTBE*, ETBE*	EtAc [§] , MEK*, MIBK*, Toluene*, cyclohexane*, methanol*	MIBK*	n-hexane*
Formulation	✓	✓	✓	✓
Automotive fuel use (IND, PROF, CONS)	✓			
Spray uses (IND, PROF)		✓		
Non-spray uses (IND, PROF)		✓	✓	✓
Laboratory use (IND, PROF) Heat transfer fluids (PROF)		✓	✓	
Cleaners, Heat transfer fluids (CONS)		✓	✓	
Domestic fuel, small quantities, coatings, screen wash, cosmetics (CONS)		✓		

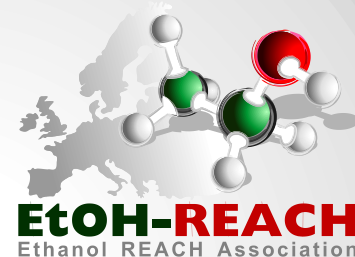
*at 5%, §at 5% and 25%, ‡at any concentration and assuming benzene always <0.1%.

Denatured ethanol



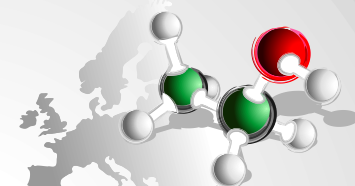
- Task 3b: Develop specific scenarios for these specific denaturants and uses
 - As now mixtures, specific exposure and RCR calculations removed from ES to allow maximum flexibility and co-use.

Denatured ethanol



- First set of 'base' generic ES produced:
 - 'D0' version: for use of any not 'hazardous' denaturant up to 1%.
 - This is compliant with Article 14 which states that, under certain conditions, no CSA required for a component up to 1%
 - For example, covers use of DEP and MIPK (and other denaturants) up to 1%
 - No RCRs shown – left effectively as a qualitative assessment

Denatured ethanols - specific ES

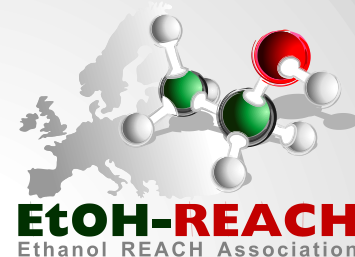


Ethanol-REACH
Ethanol-REACH Association

Exposure scenario	Gasoline	MTBE	ETBE	Ethyl acetate		MEK*	MIBK	Toluene	Cyclo-hexane	Methanol	n-hexane
	0-85%	0-5%	0-5%	5-25%	0-5%	0-5%	0-5%	0-5%	0-5%	0-5%	0-5%
ES2	ES2-D4	ES2-D2	ES2-D2	ES2-D2	ES2-D1	ES2-D1	ES2-D1	ES2-D1	ES2-D1	ES2-D3	ES2-D5
ES3	ES3-D6	ES3-D5	ES3-D5	ES3-D7	ES3-D1	ES3-D1	ES3-D1	ES3-D1	ES3-D4	ES3-D2	ES3-D3
ES4				ES4-D4	ES4-D1	ES4-D1	ES4-D1	ES4-D1	ES4-D1	ES4-D2	ES4-D3
ES5				ES5-D1		ES5-D1		ES5-D1	ES5-D1	ES5-D2	
ES6a	ES6a-D2	ES6a-D1	ES6a-D1								
ES6b	ES6b-D2	ES6b-D1	ES6b-D1								
ES7				ES7-D4	ES7-D1	ES7-D1	ES7-D2	ES7-D1	ES7-D2	ES7-D3	ES7-D4
ES8				ES8-D1		ES8-D1		ES8-D2	ES8-D1	ES8-D3	
ES9a	ES9a-D1	ES9a-D2	ES9a-D2								
ES9b					ES9b-D1	ES9b-D1		ES9b-D1	ES9b-D1	ES9b-D2	
ES9c					ES9c-D1	ES9c-D1		ES9c-D1	ES9c-D1	ES9c-D1	
ES9d					ES9d-D1	ES9d-D1	ES9d-D1	ES9d-D1	ES9d-D1	ES9d-D1	
ES9e					ES9e-D1	ES9e-D1		ES9e-D1	ES9e-D1	ES9e-D1	
ES9f					ES9f-D1	ES9f-D1		ES9f-D1	ES9f-D1	ES9f-D1	
ES9g					ES9g-D1	ES9g-D1	ES9g-D1	ES9g-D1	ES9g-D1	ES9g-D1	
ES9h					ES9g-D1	ES9g-D1		ES9g-D1	ES9g-D1	ES9g-D1	
ES10				ES10-D1	ES10-D1	ES10-D1	ES10-D1	ES10-D1	ES10-D1	ES10-D2	
ES11				ES11-D1	ES11-D1	ES11-D1	ES11-D1	ES11-D1	ES11-D1	ES11-D2	

Red = 0-4%, Blue = 4-20%. * also covers EU complete denaturant.

Denaturants

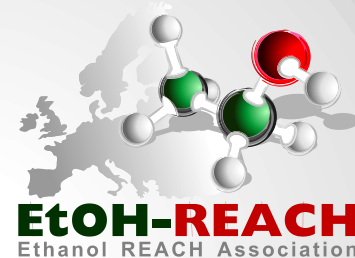


- Forward programme
 - Master versions complete
 - Translations will be made available plus instructions on how to choose and use.



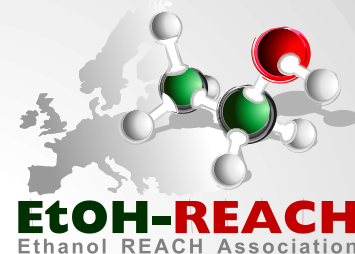
Classification and labelling inventory - update





Classification and labelling inventory



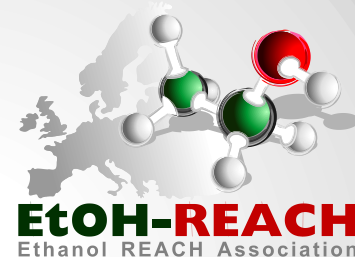
- Published 13th Feb 2012. Immediately apparent many problems with it.
- Main generic issues:
 - Did not include ‘no classification’ submissions.
 - Did not filter out nonsense notifications.
 - Mixed up polymer and monomer classifications.
 - ‘Contamination’ of classifications due to impurities.
 - No mechanism by which industry could try to harmonise classifications.
 - Ethanol specific: no indication of number of submitters of each classification

Classification and labelling submitted by Association



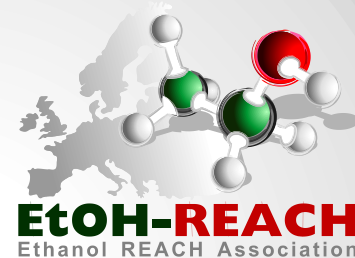
Current listed classification) under directive 67/548	Harmonised classification indicated in regulation 1272/2008 Annex VI.	Classification as indicated by the available data that is to be included in the IUCLID dossier submission
F R11	H225	H225, H319
Highly flammable 	Highly flammable liquid and vapour. 	Highly flammable liquid and vapour. Causes serious eye irritation  
		Specific concentration limit: >50%: H319

Ethanol classification – current notifications



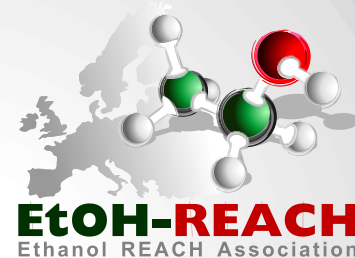
	Number
Total number of notifiers	5210
Total number of different classifications	37
...of which classifications supported by only 1 notifier	18
Harmonised (flammable only)	3843
As supported by consortium (flammable, eye irritant >50%)	543
Flammable and eye irritant without the 50% SCC	510
Number of notifiers including a CMR classification	9

Classification and labelling inventory



- Inventory updated and republished later in 2012
- Status on main generic issues:
 - Did not include ‘no classification’ submissions. -FIXED
 - Did not filter out nonsense notifications.
 - Mixed up polymer and monomer classifications.
 - ‘Contamination’ of classifications due to impurities.
 - No mechanism by which industry could try to harmonise classifications. -FIXED
 - Ethanol specific: no indication of number of submitters of each classification -FIXED

Classification and labelling discussion platform

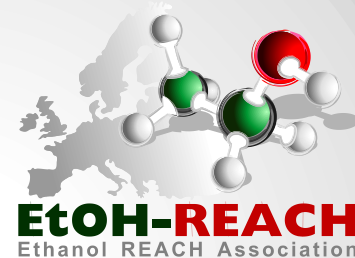


- Made available by ECHA late 2012
- Provides a platform in which notifiers can discuss and agree(?) a classification
- Only accessible by those who have notified
 - Need to login using REACH-IT password
- Not much more than a chat room
 - Notifiers are sent an email advising them when a discussion is started but then onus on notifier to take part.
- The Association has decide not to start such a discussion as it is not possible to control once underway.
 - Experience so far is that it is unlikely to work as a process.



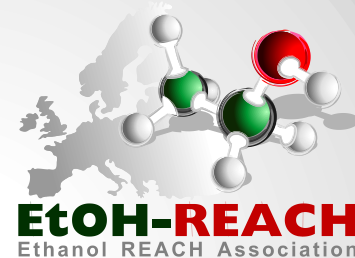
Classification and labelling - Biocidal Products Regulation

Classification and labelling: Greece and biocides review - 1



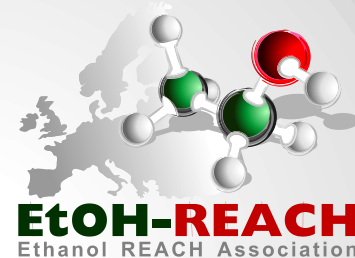
- Biocidal Products – Directive (BPD) replaced by Regulation (BPR) in September 2013
- 2 Biocides consortia:
 - Task Force Alkohole (TFA)
 - ASD Consortium Alcohol (ASD)
- TFA dossier under review by Greece competent authority
- ASD dossier due September 2013

Classification and labelling: Greece and biocides review - 2



- Greece must submit Annex XV dossier to ECHA on C&L
- We understand that this may propose CMR classification of ethanol by oral route
- Severe potential impact upon downstream use sectors
- Note: classification not normally defined by route!

Classification and labelling: Greece and biocides review - 3

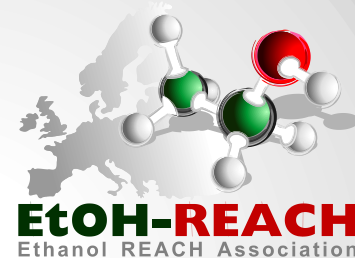


- Evaluation Task Force informed
- Ethanol producers alerted
- DU sectors engaged, eg detergents & cleaning, cosmetics...
- Proposal more difficult to tackle after Annex XV submission to ECHA
- Need to have constructive discussion soon with Greek authorities
- Concerted action planned by EtOH REACH Association, Ethanol industry, both consortia, DU organisations



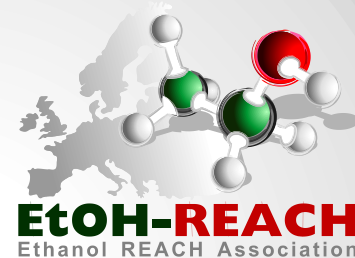
Technical programme 2012-2013

Update on activities - 1



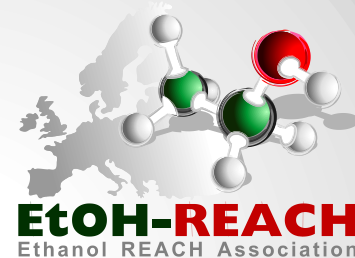
- Webinar run end January
 - 28 Participants
- Guidance updates
 - No updates. ECHA promises no changes within 6 months of a registration deadline
- Evaluation task force – maintain as active
 - Communications undertaken advising of Greek situation
 - Scope extended to cover C&L issues only

Update on activities – 2



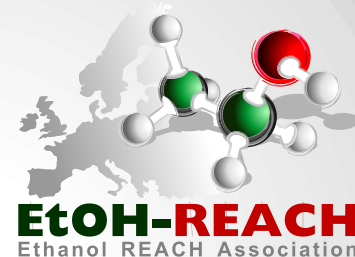
- Ethanol not on CoRAP list, but a number of known denaturants are:
 - Methanol (2012 – PL – suspected reprotoxicity)
 - Toluene (2012 – FI – suspected CMR and other toxicity concerns)
 - n-Hexane (2012 – DE – suspected CMR and neurotoxicity)
 - Diethyl phthalate (2014 – DE/PT - suspected endocrine disruptor)
 - Methyl t-butyl ether (2014 – FR - suspected endocrine disruptor)
 - t-butanol (2013 – UK - may be related to carcinogenicity)

Update on activities – 3



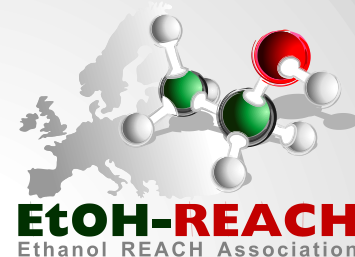
- Substance review programme
 - Revised CoRAP issued in Feb
 - Draft report methanol just issued
- Classification and labelling
 - Italy has submitted its methanol proposal to ECHA
 - Sweden has also submitted linalool proposal.
- Support to members and secretariat leading up to May 31st registration deadline

Update on activities – 4



- Briefing notes for members:
 - Registering ethanol outside the SIP
 - Late registration & options available
 - Update on exposure scenarios for denatured ethanol & options available.
- Support to members and secretariat leading up to May 31st registration deadline.

Plan for remainder of 2013

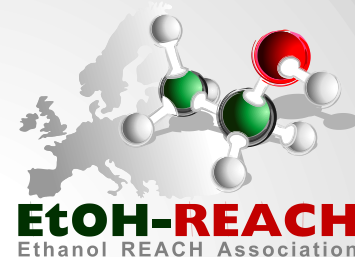


- Literature search mid year covering past 12 months
- Exposure scenarios – potential new use (insect repellants)
- Update to IUCLID 5.4
 - v5.4 introduces many new fields. ECHA has indicated that many of these will become mandatory in the future. Main ones of concern still to be addressed:
 - Exposure scenarios: These now need to be documented in full in IUCLID (new chapter 3.7). Many fields to complete!
 - End point summaries. Many new structured fields. Toxicology summary requires documentation and justification of all assessment factors used
 - TCC quality check still does not cover these so may postpone until 2014



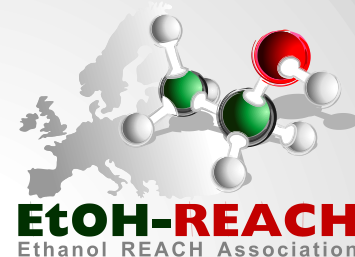
REACH fees regulation

REACH fees regulation

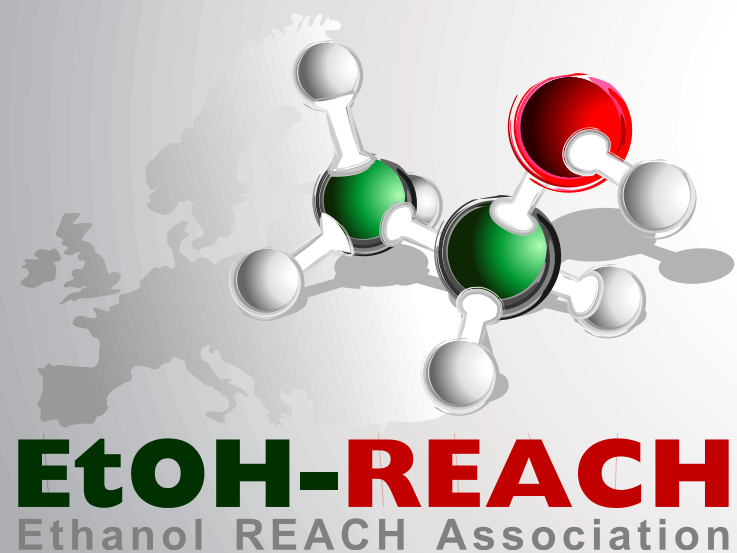


- Fees for REACH registration deliberately specified in a free standing regulation to allow easy update
- First regulation 340/2008
- New regulation updating fees issued 20/3/2013 (regulation 254/2013)
 - Arrived with little warning
 - New fees came into force immediately

Headline changes



- All fees for non SME's increased (7.1%)
- SME fees decreased (0.5%)
- Scope for charging under point (xi) of Article 10(a) increased
 - Number of things that are subject to confidentiality fees.
- Commission have signalled intention to review fees again in 2015.

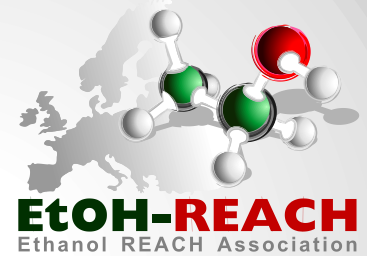


EtOH REACH General Assembly 2013

Associated substances

Steffen Krämer
Executive Committee member of the Ethanol REACH Association

Associated substances supported by EtOH-REACH



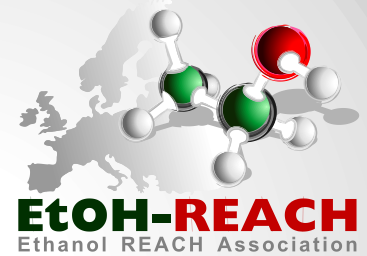
- EtOH-REACH decided to help to facilitate the registration of **Fusel oil** and **Vinasse**
 - separate budget
 - separate fee
- forming sub-consortias



EtOH-REACH
Ethanol REACH Association

Vinasse

Five different Vinasse substances supported by EtOH-REACH



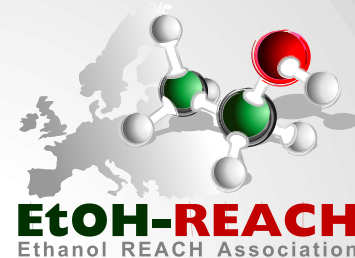
A) Biomass removed:

1. 932-215-9 Vinasses, residue of fermentation
2. 932-176-8 Vinasses, residue of fermentation, salt-enriched.

B) Biomass not removed:

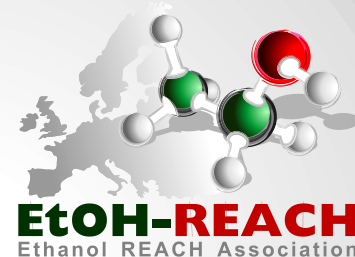
1. 932-161-6 Vinasses, residue of fermentation containing biomass of bakers yeast (*Saccharomyces cerevisiae*)

Status



- 36 members, 2 sold LoA
- Stay prepared to respond ECHAs requests
- Present ca. 1 week before Christmas – response time 14 days!

ECHA compliance check



- Four Lead registrants got a NOTIFICATION OF A DRAFT DECISION ON A COMPLIANCE CHECK UNDER REGULATION (EC) NO 1907/2006:
missing partition coefficient n-octanol/water (Log Kow)
 - submitted justification not accepted by ECHA
- Preparation of scientific based "Log Kow statement" by WIL Research
 - Update of IUCLID section 2.3 due to the new TCC, Adaption of the CSR, templates for sections 1 – 3)
 - ECHA meanwhile accepted

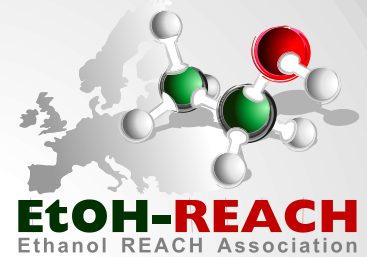


EtOH-REACH
Ethanol REACH Association

The logo features a 3D ball-and-stick model of an ethanol molecule (CH₃CH₂OH) with green spheres for carbon, white for hydrogen, and a red sphere for oxygen. This is positioned above a faint, grey map of Europe. The entire logo is centered within a large, light-grey circular frame that has a subtle radial gradient.

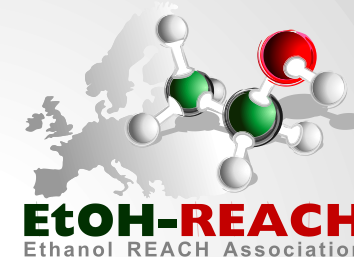
Fusel Oil

Fusel Oil



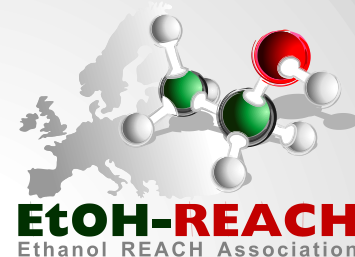
- EINECS No: 232-395-2
- UVCB substance
- Manufacturing Descriptions for the CSR:
 - Fusel Oil is produced as by-product when an Raw Ethanol Solution is passed through a distillation train to remove impurities and water, whereas the Fusel Oil, the Ethanol and the Water will separated in single streams. The Raw Ethanol Solution is commonly output of a fermentation or a synthetic process with various degrees of purity.

Substance Identification Profil (SIP)



CONSTITUENT	CLASSIFICATION AND LABELLING	PROPOSED CONCENTRATION RANGE [% (w/w)]
Ethanol (64-17-5)	F; R11	> 0.01 - < 65
3-methylbutan-1-ol (123-51-3)	not legally classified	> 10 - < 85
2-methylbutan-1-ol (137-32-6)	not legally classified	> 1 - < 25
2-methylpropan-1-ol (78-83-1)	Xi; R10, R37/38, R41, R67	> 0.01 - < 30
Propan-1-ol (71-23-8)	F, Xi; R11, R41, R67	< 10
1-Butanol (71-36-3)	Xn; R10, R22, R37/38, R41, R67	< 1.5
Butan-2-ol (78-92-2)	Xi; R10, R36/37, R67	< 2
Ethyl acetate (141-78-6)	F, Xi; R11, R36, R66; R67	< 5
Isopentyl acetate (123-92-2)	R10, R66	< 0.5
Methanol (67-56-1)	F, T; R11, R23,24,25, R39/23/24/25 (SCL)	< 1
Acetaldehyde (75-07-0)	F+, Xn; R12, R40 (Carc. Cat. 3), R36/37 (Xi)	< 0.5
2-Pentanol (6032-29-7)	not legally classified	< 0.5
Hexanol (25917-35-5)	not legally classified	< 2.5
2-furaldehyde (Furfural) (98-01-1)	Carc. Cat. 3; R40-T; R23/25-Xn; R21 - Xi; R36/37/38	< 0.5
Ethyl and isopentyl esters of fatty acids	not legally classified	each < 7
Ethyl lactate (97-64-3)	Xi; R10, R37, R41	< 0.5
Farnesol (4602-84-0)	not legally classified	< 1
...		

Fusel Oil – steps forward



- registration deadline: 2013, June
- members: currently 9 small and 5 micro members
- lead dossier submitted (payment phase)
- members will get the token and templates for chapter 1-3 by EtOH-REACH by this week



Financial reporting



Financial report 2012

	BUDGET 2012	Actual 2012
INCOME		
Membership	0	42.240
Letter of access	0	53.580
Interest	25.000	31.615
Total income	25.000	127.435
EXPENSES		
Secretarial services	50.000	70.000
ChemSage / DCL expenses	73.575	76.460
Post-registration contingency	11.035	
Evaluation taskforce	5.250	
Contingency Evaluation taskforce	42.000	
Internal Meeting expenses	23.000	6.844
Travel & stay L.A.M.	3.500	3.644
General Expenses		
Office expenses	12.925	9.597
Total expenses	221.285	166.545
RESULT	-196.285	-39.111
Capital al January 1st	1.565.777	1.565.777
Capital at December 31	1.369.492	1.526.666



Budget 2013

BUDGET 2013

INCOME

Membership	0
Letter of access	0
Interest	25.000

Total income	25.000
---------------------	---------------

EXPENSES

Secretarial services	55.000
ChemSage / DCL expenses	75.500
Post-registration contingency	14.950
Evaluation taskforce	

Contingency Evaluation taskforce	42.000
Internal Meeting expenses	23.500
Travel & stay L.A.M.	3.500

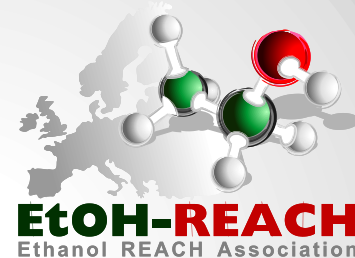
General Expenses

Office expenses	18.525
Total expenses	232.975

RESULT	-207.975
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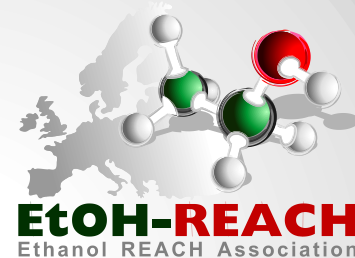
Capital al January 1st	1.526.666
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Capital at December 31	1.318.691
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Approval of the report 2012 and budget 2013

- To be voted by members





Financial report Vinasses

	Budget 2012	Actual 2012
INCOME		
Membership	3.240	
Total income	3.240	0
EXPENSES		
Secretariat	13.250	12.500
Meeting expenses	2.000	0
Dr. Knoell	0	
Travel and Stay LAM	500	0
Reimbursement of 3 companies	16.200	0
General Expenses	500	109
Total expenses	32.450	12.609
RESULT	-29.210	-12.609
Capital		68.437



Financial report/budget

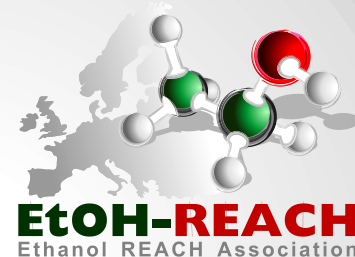
Fusel Oil

	BUDGET	ACTUAL	Projection
	2012-2013	2012	2013
INCOME			
Membership Phase 2	305.635	228.000	131.000
Total income	305.635	228.000	131.000
EXPENSES			
Secretariat	25.000	25.000	15.000
Meeting expenses phase 2	7.500	2.663	5.000
Dr. Knoell phase 2	125.000	19.809	103.000
Travel and Stay LAM	1.500	2.984	4.000
PC studies	17.600		17.600
Purchase of existing studies (max)	100.000	64.166	36.000
General Expenses	1.250		
Total expenses	277.850	114.623	180.600
Contingency 10%	27.785	11.462	18.060
Total	305.635	126.085	198.660
RESULT	0	101.915	-67.660
Capital		89.842	40.242



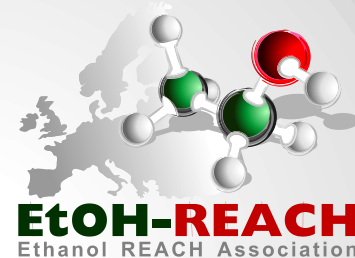
Election of officials

Proposal for composition of Executive Committee 2013



- President – Bernard Bastier, Tereos
- Vice-President – Steffen Krämer, Südzucker
- Secretary – Matthias Mundt, Euro-Alkohol GmbH
- Treasurer – Aly Rappange, Cargill
- Members:
 - Martin Burger, Abengoa Bioenergy Netherlands
 - Saeed Ahmad, Ineos

Election of officials

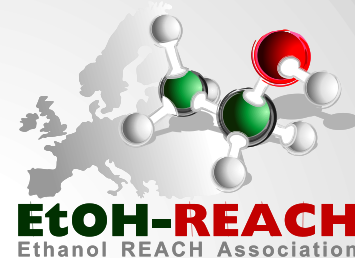


- Vacancy for importer/trader
- Proposed officials to be approved by members



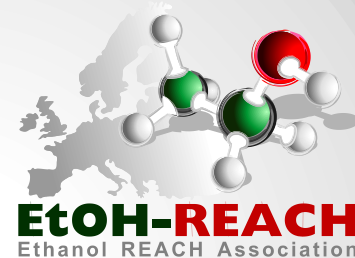
The Future of ETOH-REACH

Legal requirements



- Second registration deadline: 2013
- Evaluation procedure accelerating
 - Ethanol not (yet) directly affected
 - Important denaturants in scope
- Final deadline for registration under REACH: 2018

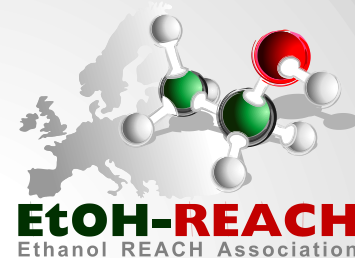
Ongoing activities



- Administration of Letter of Access/membership database
- Taskforce for Dossier evaluation
- Evaluation of need for update of Dossier
- Monitor developments in REACH and impact for members

Ongoing activities (2)

- Offer platform for related substances
- Provide information to (SIEF) members
- Support of Lead Registrant
- Launch of new website
- Forum for classification issues



Questions?

