Summary

- ECHA issued final decision letters on all substances in Categories 1, 2, 3 and 4 which mandated new animal testing
- The initial testing program is due to complete this summer (2016)
- The cost for this testing program must be shared equally by all registrants of the substances which were issued with final decisions
- This letter contains information about how the costs were shared
- Further testing (OECD 443 Extended Generation Reprotoxicity Study) is expected in the near future. This will apply only to registrations of 1000 tonnes and above

Background

As you will be aware ECHA issued draft decisions on 20 substances registered by the H4R Consortium. This process began in July 2011 and we have been working with the lead registrants and ECHA to resolve the issues within ECHA's regulatory process and timeframe.

In April 2013 each of the lead registrants submitted an updated dossier to ECHA supporting and strengthening the category approach as well as containing test proposals to cover the information requirements in question. We communicated with all co-registrants in 2013 to provide as much notice of costs in advance as possible.

The testing proposals the minimum amount of testing possible to cover the relevant endpoints and included the provision of screening information designed to limit the overall amount of higher tier (more expensive) testing to meet the needs of the revised category. The alternative would be to have to conduct every study for every substance.

The testing proposals were accepted by the Member States Committees at a meeting in June 2014 and final decisions were issued on all testing proposals to the lead registrants in August 2014. The testing plan will complete this summer (2016).

Revenue from Letters of Access Held to Cover Testing Costs

Due to the cost of the proposed testing, the Steering Committee of the H4R Consortium decided to hold the revenue generated by the sale of letters of access against the costs of the upcoming testing programme. This has been done to save all members and co-registrants the cost of disbursing revenue which then has to be reclaimed by raising invoices.

As per the SIEF agreement, all co-registrants are equally responsible for all additional costs above €1,000 and co-registrants will receive an invoice as detailed in the tables below.

Penalty for Non Payment of Testing Costs by Co-Registrants

All Co-Registrants are liable for payment. If payment is not received within the terms and conditions stated, the lead registrant will revoke the right to use the data provided and ECHA will be informed. Legal action will follow to recover the costs.

Category Approach

In 2010, the H4R Consortium defined a category approach with some substances providing read across data to other similar substances in the same category. Dossiers submitted in 2013 also used data in a read across approach and used data from substances registered in 2010. Therefore, the testing program supports the category approach for all H4R Consortium substances and will also inform registration of H4R Consortium substances in 2018.

Supportive Work

In addition to the testing program, ECHA agreed with the Consortium in to do additional supportive work and a program designed to give ECHA confidence in the overall strategy d3evceloped by H4R. This involved developing an understanding of absorption of Rosin and derivative. This inexpensive testing method also allowed the Consortium to select which substances should be tested in the higher tier program reducing overall programme costs. As such the costs for this program were divided equally by all co-registrants.

Testing Costs per Category for OECD 408 and OECD 414 Studies

The following tables show the approximate costs of the minimum amount of testing proposed per category, together with a timeline for the program. Costs will be shared as defined in the consortium and SIEF agreements. This is on a per registration basis. Each Co-registrant will pay a share of the costs per registration.

Category 1, Rosin and it's salts - REACH testing costs and timetable - Annex IX

A. Number of H4R substances and company registrations

Tonnage band	Number substances	Number of registrations (H4R and SIEF)
> 1000 t (REACH Annexe VII, VIII, IX, X)	8	56
100 - 1000 tpa (REACH Annexe VII, VIII, IX)	2	31
All	10	87

B. Testing Costs

Study	Test Unit cost	No.	Total €	Year				
				2013	2014	2015	2016	2017
					10%	80%	10%	
OECD 408 (Repeat Dose)	€ 110,000	3	€ 330,000		€ 33,000	€ 264,000	€ 33,000	
OECD 414 (Dev Tox)	€ 100,000	1	€ 100,000		€ 10,000	€ 80,000	€ 10,000	
Total			€ 430,000	€ -	€ 43,000	€ 344,000	€ 43,000	€ -

C. Indicative cost sharing

Overall Cost for per substance interest = Total cost divided by number of interests	**€ 4,943**	**€ -**	**€ 494**	**€ 3,954**	**€ 494**	

Category 2 - Rosin Esters - REACH testing costs and timetable - Annex IX

A. Number of H4R substances and company registrations

Tonnage band	Number substances	Number of registrations (H4R and SIEF)
> 1000 t (REACH Annexe VII, VIII, IX, X)	5	32
100 - 1000 tpa (REACH Annexe VII, VIII, IX)	7	31
All	12	63

B. Testing Costs

Study	Test Unit cost €	No.	Total €	Year 2013	2014	2015	2016	2017
Payment schedule					10%	85%	5%	
OECD 408 (Repeat Dose)	€ 110,000	2	€ 220,000		€ 22,000	€ 187,000	€ 11,000	
OECD 414 (Dev Tox)	€ 100,000	5	€ 500,000		€ 50,000	€ 425,000	€ 25,000	
Total			€ 720,000	€ -	€ 72,000	€ 612,000	€ 36,000	€ -

C. Indicative cost sharing

Overall Cost for per substance interest = Total cost divided by number of interests	**€ 11,429**	**€ -**	**€ 1,143**	**€ 9,714**	**€ 571**	**€ -**

Category 3 Category 3 - Rosin adducts and rosin adducts salts - REACH testing costs and timetable - Annex IX

A. Number of H4R substances and company registrations

Tonnage band	Number substances	Number of registrations (H4R and SIEF)
> 1000 t (REACH Annexe VII, VIII, IX, X)	4	11
100 - 1000 tpa (REACH Annexe VII, VIII, IX)	1	6
All	5	17

B. Testing Costs

Experimental costs (Indicative)	Unit cost €	No.	Total €	Year 2013	2014	2015	2016	2017
Payment schedule					10%	85%	5%	
OECD 408 (Repeat Dose)	€ 110,000	2	€ 220,000		€ 22,000	€ 187,000	€ 11,000	
OECD 414 (Dev Tox)	€ 100,000	1	€ 100,000		€ 10,000	€ 85,000	€ 5,000	
Total			€ 320,000	€ -	€ 32,000	€ 272,000	€ 16,000	€ -

C. Indicative cost sharing

Overall Cost for per substance interest = Total cost divided by number of interests	**€ 18,824**	**€ -**	**€ 1,882**	**€ 16,000**	**€ 941**	€ -

Category 4 - Rosin Adduct Esters - REACH testing costs and timetable - Annex IX									
A. Number of H4R substances and company registrations									
Tonnage band			Number substances		Number of registrations (H4R and SIEF)				
> 1000 t (REACH Annexe VII, VIII, IX, X)			3		4				
100 - 1000 tpa (REACH Annexe VII, VIII, IX)			1		10				
All			4		14				
B. Testing Costs									
Study	Test Unit cost €	No.	Total €	Year					
				2013	2014	2015	2016	2017	
Payment schedule					10%	90%			
OECD 408 (Repeat Dose)	€ 110,000	3	€ 330,000		€ 33,000	€ 297,000			
OECD 414 (Dev Tox)	€ 100,000	1	€ 100,000		€ 50,000	€ 50,000			
Total			€ 430,000	€ -	€ 83,000	€ 347,000	€ -	€ -	
C. Indicative cost sharing									
Overall Cost for per substance interest = Total cost divided by number of interests			**€ 30,714.29**	**€ -**	**€ 5,928.57**	**€ 24,785.71**	**€ -**	**€ -**	

How is the Final Amount per Co-Registrant Calculated?

The final amount per registrant must take into account any Settlement figures (revenue from the sale of letters of access) from previous years against each Co-registrant's share of the testing cost. Therefore a personal statement has been prepared for each Co-registrant which you will have received with an invoice for payment.

Example of costs worked out for Registrants in Different Tonnage Bands

Category	CAS Number	Name	Co-Registrant Details	Tonnage Band of Registration	Settlement Figure to May 2013	Settlement Figure to End 2014	Testing Cost Share Per Registration (OECD 408 + OECD 414)	Testing Cost Share for OECD 422 Screening	Testing Cost Share for Supportive Intestinal Absorption Testing	17 % Sweat Equity Charge	Amount Outstanding To Be Paid
1	8050-09-7	Rosin	Company A, Address from records	>1000 tpa	€ 1,821.00	€ 1,240.00	€ 4,943.00	€ 4,964.96	€ 387.00	€ 1,750.14	-€ 8,984.10
1	8050-09-7	Rosin	Company B, Address from records	100 to 1000 tpa	€ 1,821.00	€ 1,240.00	€ 4,943.00	€ 4,964.96	€ 387.00	€ 1,750.14	-€ 8,984.10
1	8050-09-7	Rosin	Company B, Address from records	10 to 100 tpa	€ 3,877.00	€ 1,240.00	€ 0.00	€ 4,964.96	€ 387.00	€ 909.83	-€ 1,144.79

Future Costs

When the current program is complete we will issue another invoice to cover the costs of additional histopathology, other testing and other work that has been completed as part of the program. This figure will be calculated at the end of this program and the invoice will be sent in Q4 of 2016.

ECHA's Final Decisions on OECD 443 Extended One Generation Reproductive Toxicity Study

H4R Consortium proposed to do OECD 416 Reproductive Toxicity Study to cover the endpoints needed for >1000 tpa dossiers and this was agreed in 2013.

Subsequently ECHA and the Member States favour a one generation study (OECD 443) and the regulation was changed by the EU Commission in January 2015[1]. However, H4R Consortium have yet to be notified formally that this testing should be carried out and no decision letters have been received by Lead Registrants as of September 2016. When the EU Commission informs H4R Consortium by releasing final decisions, H4R will communicate with you about the costs of that program which are likely to be more that the original projected costs for the 2 generation studies.

We would not expect the work on the one generation studies to start until 2017 at the earliest.

If you have any questions, please contact manager@h4rconsortium.com

[1] COMMISSION REGULATION (EU) 2015/282 of 20 February 2015 amending Annexes VIII, IX and X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards the Extended One-Generation Reproductive Toxicity Study