出國報告（出國類別：考察）

歐洲化學總署
第 12 屆利害關係人會議

服務機關：行政院環境保護署毒物及化學物質局
姓名職稱：金承漢技士
派赴國家：芬蘭
出國時間：106 年 4 月 1 日至 4 月 8 日
報告日期：106 年 7 月 6 日

摘要

本次赴芬蘭赫爾辛基參加歐洲化學總署(European Chemicals Agency, ECHA)第12屆利害關係人會議(stakeholder's day)，瞭解歐盟現行化學品註冊、評估、授權和限制(Registration, Authorization and Restrication of Chemicals, REACH)法規制度，及其與利害關係人之溝通協調，REACH將於2018年截止針對境內運作物質達到1噸以上（1-10噸與10-100噸）的分階段註冊，藉由本次會議參與可望對於歐盟化學品政策趨勢與未來走向增進理解，並瞭解ECHA與利害關係人溝通模式，以其經驗作為參考，加強我國對於化學物質之管理整合與跨部門合作，重視各利害關係人的參與及溝通，精進我國化學物質登錄政策。

行程亦安排拜訪ECHA與芬蘭安全與化學局(Finnish Safety and Chemicals Agency/ Turvallisuus- ja kemikaalivirasto, Tukes)，透過與ECHA專家交流瞭解歐盟及各會員國間對於化學品的管理模式與互動合作，包含美國化學文摘社(Chemical Abstracts Service, CAS)編號資料之應用、非動物之替代測試方法(non-animal testing)的經驗、未知或可變成分與複雜反應或生物材料(unknown or variable composition, complex reaction products and biological materials, UVCB)物質的註冊管理、官方在共同註冊所扮演角色及跨部會合作方式。而與Tukes的交流則著重在查核執法行動的計畫與安排，投入之人力與資源及實務管理的瞭解，除配合ECHA執行REACH法規及非食品類消費品快速通報系統(Rapid Alert System for dangerous non-food products, REPEX)等計畫或措施施行外，並針對芬蘭的化學品使用與產業特性規劃目標，且均以風險管理的概念評估進行策略設定。

REACH制度自實施以來，廣納利害關係人參與，與利害關係人的溝通扮演不可或缺的角色，加強與之共識，建立良好的互動管道與平臺，才能建構符合國家未來發展及國際間共同努力之方向發展化學品管理制度。鑑於全球對於化學品規範重視的成長，且最小化負面效應與具備永續性的管理目標成為主流，持續關注國際議題與動態積極交流合作，瞭解其他國家在制度架構設計上的安排與所面臨之挑戰，能從中參考學習，致力於我國永續發展與環境品質提升。

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歐洲化學總署(European Chemicals Agency, ECHA)自西元2008年起，每年例行舉辦利害關係人會議(Stakeholders' Day Conference)，該會議提供ECHA傳達最新動態，化學品註冊、評估、授權和限制法規(Registration, Evaluation, Authorization and Restriction of Chemicals, REACH)有關資訊，並作為良好平臺與參與者溝通交流，蒐集相關回饋建議，確認制度能服務，每年利害關係人會議參與者多包含業界、非營利組織、技術顧問單位，及非歐盟國家主管機關等。

我國於102年12月11日修正公布之毒性化學物質管理法，及次年開始啟動實施之新化學物質及既有化學物質資料登錄辦法，均有一定程度係參考歐盟REACH註冊之架構與精神，藉由利害關係人會議與國際交流外，並能瞭解ECHA在推動REACH制度過程的經驗與未來趨勢。本（第12）屆利害關係人會議於芬蘭赫爾辛基的歐洲化學總署舉辦，本次出國行程主要目的如下：

一、蒐集歐盟化學品管理資訊

我國為與國際接軌，已正式實施化學物質登錄制度，歐盟REACH法規架構為我國化學品管理的重要參考依據，因此ECHA於REACH實施以來，面臨到的挑戰、執法現況、落實情形以及應對方式等，均對我國有重要的參考價值，值得透過本次參訪進行交流學習，作為我國後續制度調修之參考。

二、瞭解歐盟未來化學品政策走向趨勢與預期未來影響

歐盟REACH將於2018年截止針對境內運作物質達到1噸以上的分階段註冊，因此對於2018年註冊截止日後，ECHA未來管理方向與執行藍圖，都將是所有參考歐盟REACH建立化學品管理政策國家的關注焦點，此外，歐盟化學品管理法十分完整且縝密，藉參與本次利害關係人會議，可對於我國未來化學品評估管理政策展望有進一步的架構推展。

三、瞭解歐盟與利害關係人溝通互動模式

該會議針對REACH註冊檔案提交與管理、評估、授權、限制和執法現況及常見問題等，從不同利害關係人角度切入，與會者包括了業界、非營利組織、技術顧問單位，及非歐盟國家主管機關等，討論主題和參與層面亦相當廣泛。以歐盟與利害關係人溝通互動狀況與經驗，可作為我國在相關政策推行之借鏡。

貳、 過程

本次行程前往芬蘭赫爾辛基，主要依序至歐洲化學總署(ECHA)參訪交流、參與本（第12）屆利害關係人會議，及至芬蘭安全與化學局(Tukes)參訪交流。

一、歐洲化學總署(ECHA)拜訪

本次於利害關係人會議前一日，由ECHA的Makela博士安排與ECHA的職員針對化學物質登錄與管理進行雙邊討論會議，除向ECHA分享我國登錄制度推展現況外，討論之主要主題如下包括：美國化學文摘社(Chemical Abstracts Service, CAS)編號使用於資料庫查詢相關規範、非動物替代測試方法(Non-animal testing)的實際情形與技術內容、未知或可變成分與複雜反應或生物材料(unknown or variable composition, complex reaction products and biological materials, UVCB)物質之評估方式及官方在共同註冊所扮演角色等。會議中ECHA針對各項問題提供其目前情形與施行經驗，我方並就我國現況進行意見交換，有相當充分的討論並得到寶貴經驗，俾作為我國化學物質之登錄、評估與管理政策參考。

對於CAS編號的應用，ECHA表示在其經驗，無論是個人或組織，在無收費的情況下可以無償使用1萬筆CAS編號，包括公開在網頁、型錄或其他產品相關的應用，若超過1萬筆化學物質，則需向CAS取得授權。另ECHA與CAS之間的授權關係並無涉及相關費用，單純以歐盟REACH制度下的各種化學物質清單介接作為交換。

而在非動物之替代測試方法的經驗上，主要討論到交互比對法(Read-across)與定量構效關係(Quantitative structure - activity relationship, QSAR)之應用：（一）交互比對法在REACH的註冊資料中使用頻率相當頻繁，約有75%的註冊案件計11,998個物質有使用該方法，其中69%為單一組成物質，10%為多組成物質，21%是UVCB物質。資料經審查或評估後可能被要求補正或退件

的原因主要包括：缺乏支持性的佐證資訊、沒有系統化的暴露細節、與科學學理有所衝突或物質辨識資訊有誤等。另外ECHA有提供完善的指引手冊－交互比對法評估架構(Read-Across Assessment Framework, RAAF)，供相關業者作參考遵循。在評估方面，ECHA內有2組審查人員分別進行初審及複核，做出決定或建議後在指定期限內由業者回覆補充或更正，而註冊文件的通過與否仍與個別案件的資料品質有絕大關係；（二）應用定量構效關係提交的註冊資料量，雖相較交互比對法較少，但特別在生態毒理的部分，有相當多的應用。在審查或評估定量構效關係的資料時，需注意其適用範圍，特別是在毒理資訊上，有些測試項目因為毒性或動力機制的關係，無法使用QSAR做模擬預測。相較注重化學與毒理專業的交互比對法，ECHA在定量構效關係方面所倚重之人力較偏重於資訊與電腦專業。

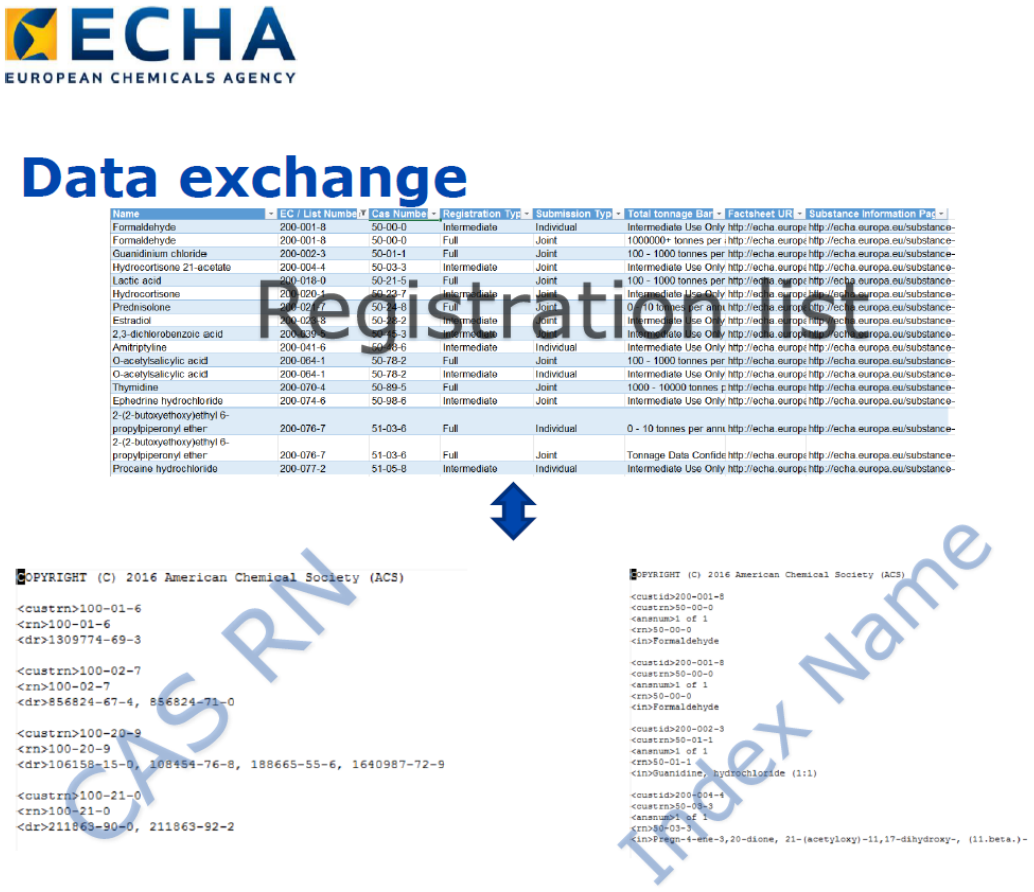

圖 1　CAS 與 ECHA 資料交換示意

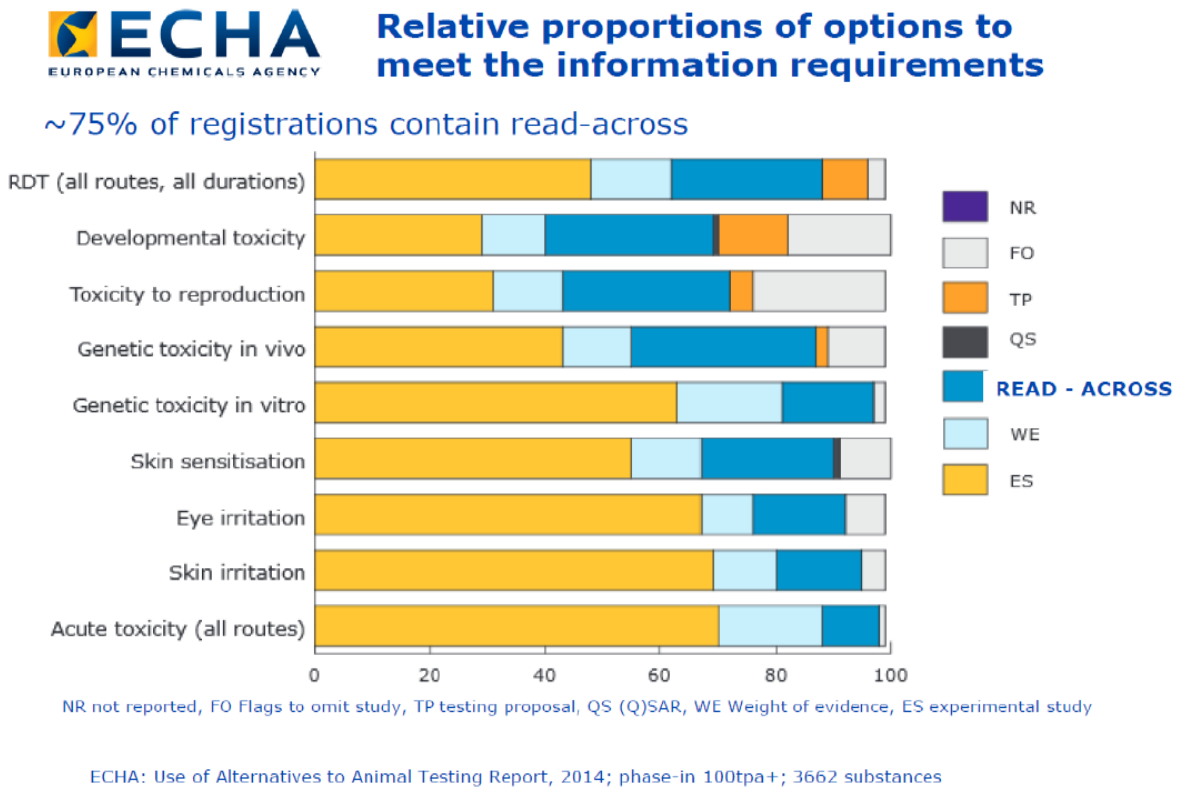

圖 2　替代測試方法在 REACH 註冊資料中使用情形

而在UVCB方面，由於其物質的組成複雜，又依各種條件如製程等，可進一步區分為許多群組，主要的群組有長短碳鏈類、石化煉油類與酶類等。由於UVCB在組成上有種種複雜之因素影響，難有簡單的制式化審查原則，因此ECHA之原則主要係要求業者繳交儘量可能完整的資料，包括反應起始物、來源、比例、反應機制、操作參數、溶劑、萃取、純化與物化特性等資訊，就科學學理上所具備之證據，做物質辨識資訊等較個案性的認定評估。

而ECHA官方在共同註冊所扮演的角色上，由於REACH制度採取一物質一註冊(one substance, one registration, OSOR)之原則，故係強制性要求共同註冊，而隨著中小企業(Small and medium - sized enterprises, SMEs)的註冊人增加，領導註冊人(Lead Registrant)與共同註冊成員間爭論點增加，共同註冊也越增困難。除了現有的物質資訊交換論壇(Substance Information Exchange Forum, SIEF)與相關註冊規定外，ECHA僅透過提供建議的方式，

協助中小企業以會員身分與大型企業溝通與協調談判，進行共同註冊，同時，也有業者提出退出共同註冊的要求，這些問題除了負擔公平性外，通常出自於物質辨識或測試終點數據的差異，而個案爭議經協商討論後，亦能視情形允許，並由ECHA代替共同註冊之領導註冊人來發給進入註冊流程的同意權利。但如何在能夠幫助中小企業之同時，拿捏程度，避免涉入業者相互間爭議過深，仍係ECHA所面對較困難之問題。

二、第12屆利害人關係會議

隨著REACH法規的推動進展，每一屆利害關係人會議ECHA也規劃特定主軸展開，以不同角度切入探討，服務與協助利害關係人，並同時蒐集意見回饋。而本屆利害關係人會議時值REACH將在西元（下同）2018年截止最後一階段最小噸數級距（1-10噸與10-100噸）註冊的最後一年前，評估該級距內多數利害關係人屬中小企業，故ECHA在本屆會議主要聚焦在如何準備2018年截止的最後一階段註冊，針對中小企業提供最新的建議、指引及支援。

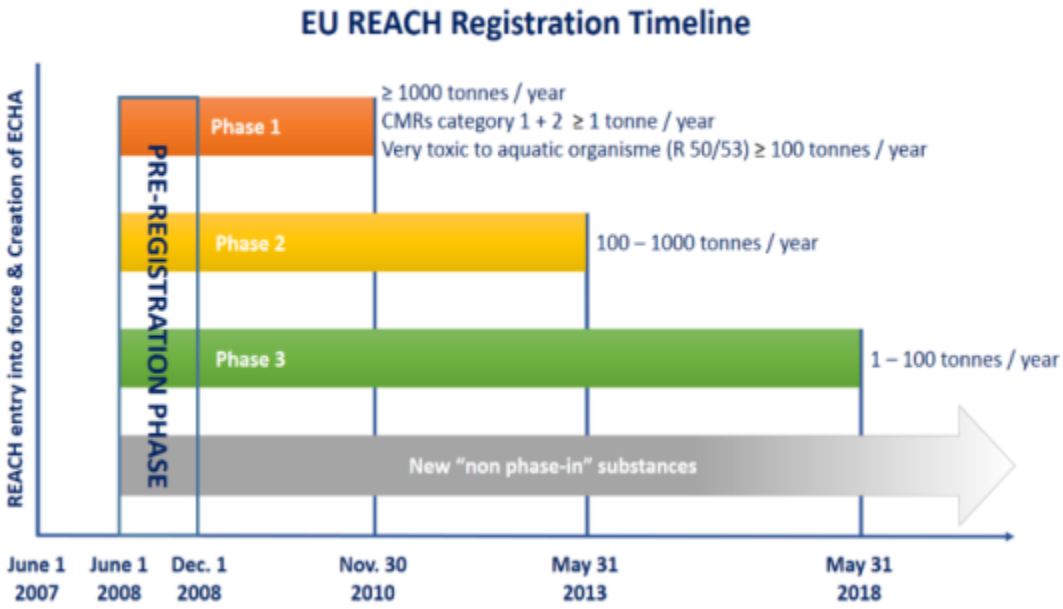

圖 3　REACH 分階段註冊噸數級距及時間

本屆利害關係人會議為期2日，第1日針對REACH註冊之資訊工具作基礎訓練課程，考量即將在2018年到期的最後一階段註冊，資訊工具的改版與訓練皆著重在中小企業為主要使用者及優化對象，訓練課程分為IUCLID(international uniform chemical information database)第6版和REACH-IT，及Chesar工具(chemical safety assessment and reporting tool)和ECHA與經濟合作暨發展組織(Organization for Economic Co-operation and Development, OECD)合作開發的QSAR-Toolbox二大部分。前者主要針對如何以IUCLID準備資料(dossier)，並在REACH-IT上提交完成共同註冊。另外ECHA也讓學員試用預計在6月正式發表的IUCLID線上版本，未來將可以方便中小企業作使用。在Chesar工具的部分，並無實機操作，改以流程方式教學需提供之資料與經驗分享。QSAR-Toolbox則有針對改版進行介紹，主要是提供了便捷的預設模組提供使用者做選擇，同樣是以中小企業使用者為對象作設計。

課程過程重點如下：

（一） IUCLID和REACH-IT的操作提供實機方式讓參與學員模擬進行共同註冊，且一開始在操作前過程中先下達任務情境，使學員更能參與融入模擬過程當中，而僅約50位學員學習操作的現場，即有將近30位助教在旁隨時提供協助與解答，更添學習效果。而IUCLID具有強大的自動檢核偵錯設計，除了基本的必填欄位檢核，對於各欄位資料交互影響所生邏輯正確性亦有檢核與錯誤警示功能。在重要更新部分，為因應REACH在2018年最後一階段註冊期限，為服務現階段較多的中小企業註冊族群，ECHA在本屆會議發布IUCLID線上版及雲端服務，與原本需下載安裝，且資料存放在個別電腦的離線版相比，線上版界面更臻簡潔明瞭，及強化操作使用彈性，較不受硬體需求限制，可隨時隨地儲存與編輯文件，並提供線上支援，期使中小企業能順利完成註冊，不過課程中可惜的是，因當日為線上

版發布首日，疑因伺服器承載負荷問題，IUCLID線上版無法讓學員順利模擬操作。

圖 4　資訊工具基礎訓練課程電腦教室

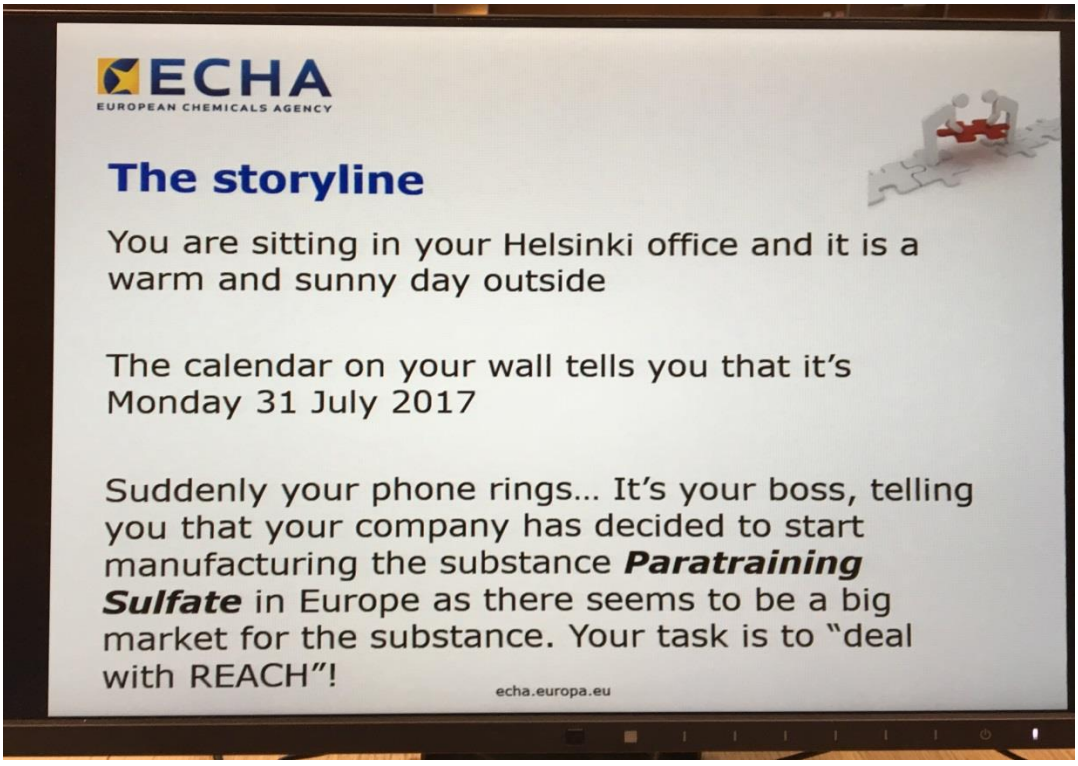

圖 5　實機模擬操作任務情境

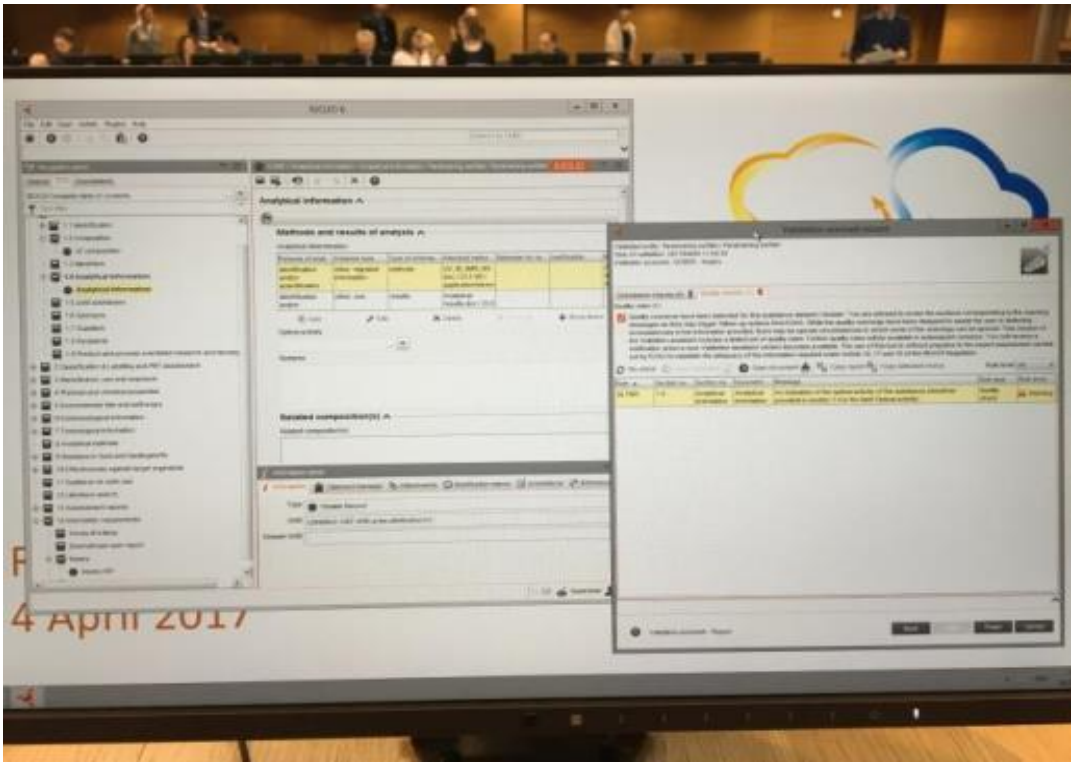

圖 6　IUCLID 檢核與錯誤警示視窗

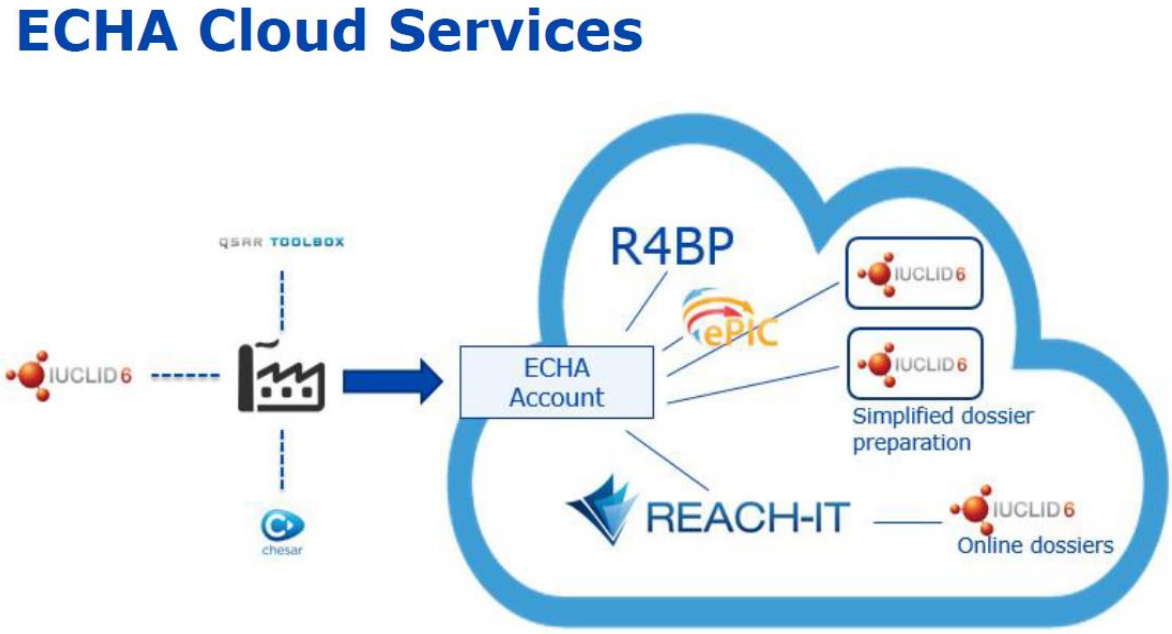

圖 7　ECHA 為中小企業設計的 IUCLID 線上版及雲端服務

（二）為使註冊人進行風險評估及化學安全報告(Chemical Safety Report, CSR)，ECHA提供了Chesar工具，註冊人可直接以IUCLID的物理化學資料與危害評估相關資料匯入，

應用Chesar工具提供的暴露情境或另外輸入的相關資料，產出風險評估結果與化學安全報告，更可進一步將資料整合產出安全資料表(Safety Data Sheet, SDS)，Chesar工具的模組化能夠使化學安全報告的產出更為簡便，但值得注意的是，許多註冊人在化學安全報告輸入過於冗長的敘述，容易造成安全資料表產出時直接帶出許多資訊重複無用的文件。Chesar工具的教學並未提供以實機演練，單純透過講解的方式使學員瞭解流程，在產出化學安全報告的過程中，除原本IUCLID的相關資料匯入外，ECHA並一再宣導強調，針對暴露的資訊，必須從供應鏈下游使用者取得正確且充足的實際使用情境，如此所產出的化學安全報告及安全資料表才能足以提供有效且正確資訊讓供應鏈傳遞。

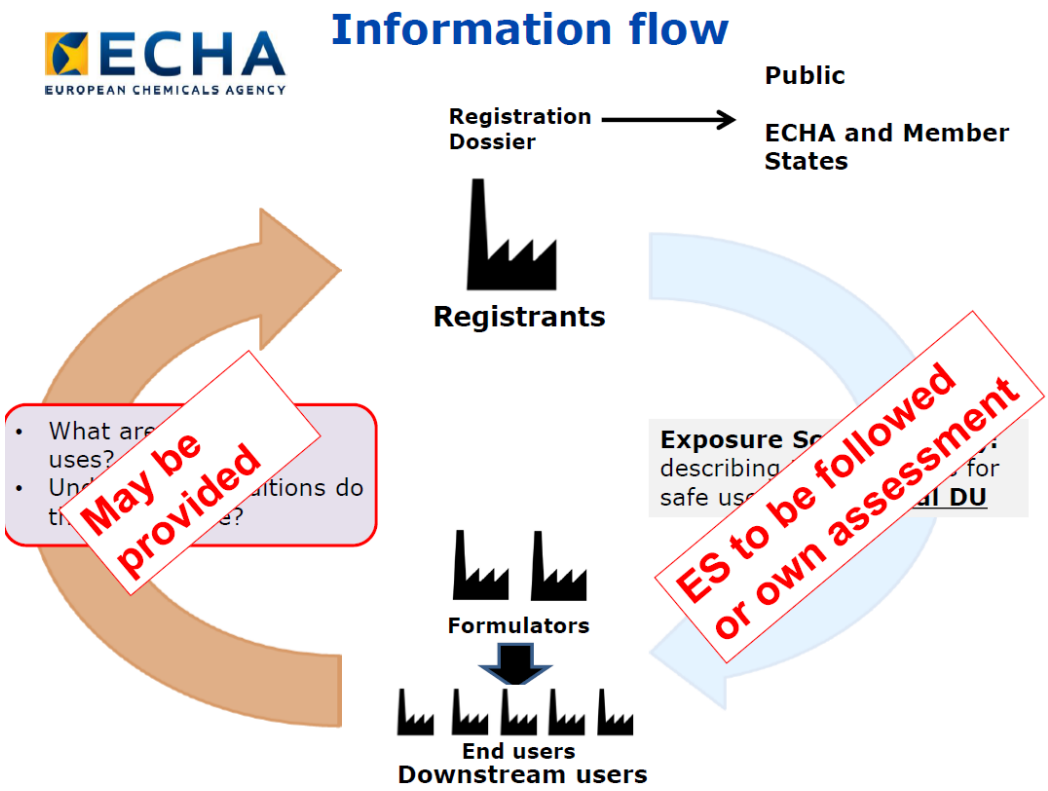

圖 8　產業上下游供應鏈資訊傳遞示意圖

第2日會議則以演講的方式進行，討論的議題除了針對中小企業面對2018年最後一階段註冊的七大步驟教學及註冊資訊工具的更新外，也請專家與業界針對物質辨識個案分析、登錄流程介紹、替代測試經驗分享、文件品質的確保、資料分享的成本、非歐盟製造國的註冊經驗、物質用途地圖與供應鏈的溝通及如何準備化學安全報告等進行分享。除現場演講直接互動外，並以網路同步直播與開放Q&A的方式進行討論，讓現場與網路上的利害關係人皆能夠與ECHA進行意見交流，同時引進slido平臺，使會議參與者更廣泛，且更為即時互動，並在會議最後能立即產出會議討論詞彙聲量等視覺化分析結果。會議共有近240個現場參與人，來自42個不同國家，超過176家公司及23個協會，並有35家中小企業與會。利害關係人會議能使官方針對不同議題各面向瞭解產業、媒體與其他相關機構的立場與意見，並做立即的適當回應與溝通。

圖 9　ECHA 執行長 Geert Dancet 開場致詞

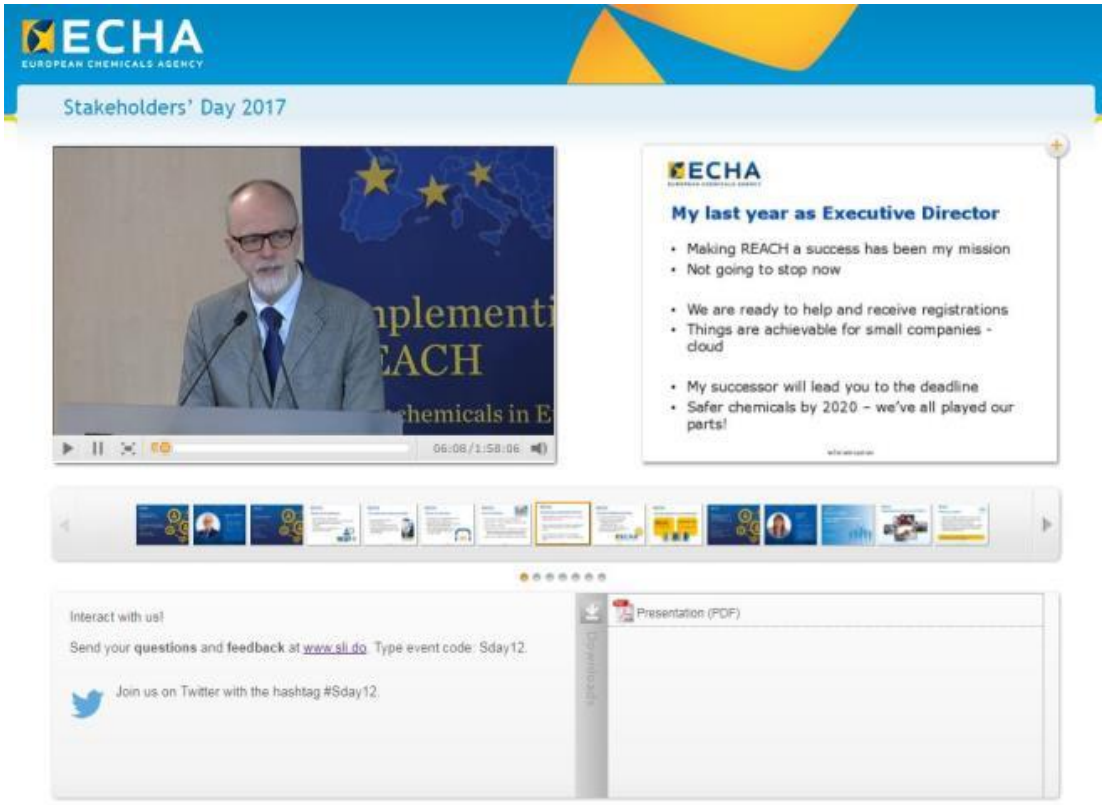

圖 10　會議情形同步以網路直播

討論議題重點如下：

（一） 完成註冊七大步驟

REACH法規施行後，已經歷過2010年及2013年止，二次截止針對較高噸數級距的化學物質註冊，2018年為最後一階段年製造或輸入1至100噸的化學物質註冊期限。ECHA將註冊過程以七大步驟說明供註冊人更能理解：1、瞭解物質的組成；2、找尋共同註冊人；3、分享數據；4、危害與風險評估；5、準備註冊文件；6、申請註冊；7、持續更新註冊資料。ECHA強調註冊雖是極具挑戰的工作，但在良好的控管下是可以完成的，重要的是在一開始就要有確實的計畫，一步步地去完成，且ECHA與各會員國也都會提供協助。

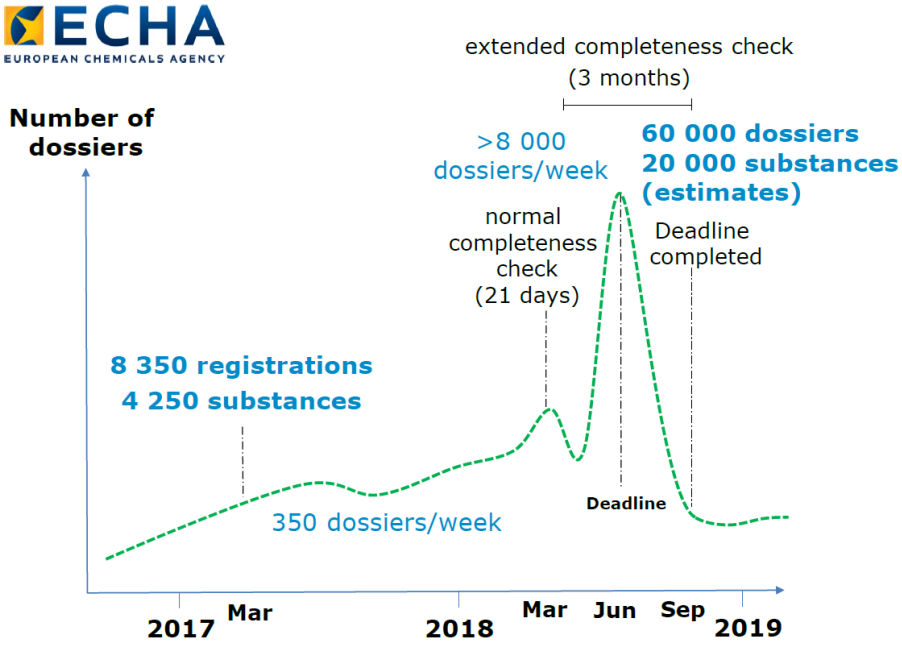

圖 11　ECHA 註冊資料繳交數量趨勢預測圖

ECHA也預期註冊案件的繳交高峰時間會落在2018年6月至9月間，平均6萬份註冊文件與2萬個化學物質將會在3個月內同時湧入，這也是IUCLID開發過程中再三強化自動檢核功能的原因，自動化省卻人工判斷的功能越是完善，註冊資料的繳交也將更加順利。

（二） 物質辨識資訊

物質辨識資訊在REACH的一物質一註冊(OSOR)原則下相當重要，不論是單一組成物質、多組成物質或是UVCB物質，都需要先確定物質本身的定義與範疇，才能夠繼續共同註冊的流程。目前ECHA常碰到的議題有其清單與國際清單的不一致、不同種類的UVCB物質的複雜程度、物質鹽類與同分異構物的關係界定等。以生質燃料的領域來說，許多非典型的原料（例如動物油或植物油）與製程，會使命名困難度相對提高，解決方式是註冊人在研發前期就將所有的物質詳細分析並進行群組歸類，並與ECHA先進行討論。此外，另一個例子是松香，自然界中的松香本身即是UVCB物質，沒有任何單一成分會超

過10%，而產製松香還會因製程不同而產生不同的衍生物，至2010年為止已經有28個相關物質進行註冊，針對松香，本身有成立一個論壇來進行討論與共同註冊。註冊的成功與否，與數據品質有絕大關係,而各共同註冊人跟物質資訊交換論壇(SIEF)的領導註冊人在前期的溝通與合作更是成功的關鍵。

（三） 替代測試經驗

減少重複測試及不必要的動物犧牲是REACH制度設計的重要精神之一，因而替代測試方法相對重要，但只有在特定的情況下能夠應用，且需經過嚴謹的檢視，常需要化學專家、毒理專家與系統分析專家共同合作討論，故在文件撰寫跟審查方面，都需要更多額外的成本付出。而較簡單的替代測試應用，通常都有幾個特點：1、物質未具複雜的雜質或副產物；2、註冊人擁有完整的相關資料；3、有相關學術文獻或報告支持；4、OECD資料庫有相關資源可供利用。因此替代測試並非一定是低成本的選擇，且資料準備需要不同的專業人員，從一開始的物質辨識來決定是否能夠在適當的項目以替代測試方式繳交資料是重要的先決條件，且業者建立屬於相關領域物質群的群組資料，不管對何種替代測試方法都相當重要。

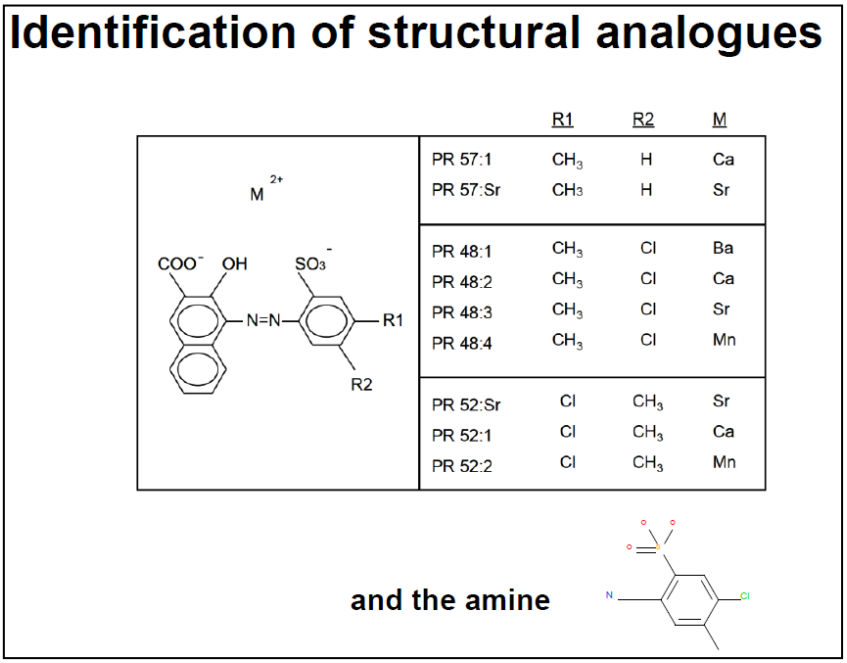

圖 12　替代測試物質辨識分析歸納範例

表 1　傳統動物實驗與替代測試比較

	standard information	**alternative strategy**
Number of Robust study summaries	one	one for each contributing study
Need for special justification	no	yes
Risk of challenge	no	yes
Suitability for other legislations (eg Water endangering class, sensitive application legislations, Korea-REACH, registrations outside EU, etc)	Accepted without discussion	Might not be accepted, or will require re-writing according to new templates/guidance, LoA for contributing studies if REACH-only
Analytics and physico-chemical properties	needed for one substance	needed for any contributing substance

（四） 資訊蒐集與共享

在註冊資訊蒐集取得部分，ECHA提出了幾點建議：1、策略及分工要明確清楚；2、在進行動物測試前要優先考慮及查明其他資訊分享或豁免的可能性；3、多與技術顧問單位溝通討論，不要僅想用最簡單的方式取得測試終點。而在資訊共享部分，ECHA給領導註冊人的建議是要儘快展開在物質資訊交換論壇(SIEF)上的溝通對話，並針對在SIEF上會員間交換的文件進行追蹤，控管所有支出的費用，以便與共同註冊人以透明公開方式討論成本負擔，且需要一併考慮內部資源的成本；而如果是身為共同註冊人的會員，則要注意每個註冊文件資料背後的可能金錢與時間成本，在SIEF提出問題時要設定合理的回

覆時間，而如非必要，退出共同註冊群組則是最後不得已才思考的方向。

（五） 境外輸入者

在歐盟境外輸入者註冊現況的主題上，由於註冊綜合成本對於中小企業來說依然是相當大的負擔，如果該物質在歐盟並無龐大市場，許多既存的供應鏈可能因為註冊人直接放棄註冊而有斷料的可能。如噸數級距在每年1至10噸者，領導註冊人之單一物質註冊成本約落在3萬6,000歐元，而每年10至1,000噸的成本則可能高達28萬歐元，倘若考慮該物質在歐盟境內的年銷售淨利低於註冊成本，業者極有可能放棄該物質在歐盟的市場。

（六） 化學安全報告(CSR)

CSR在ECHA的設計下係使用Chesar工具產出，截至2016年底大約有40%的化學安全報告是使用Chesar工具繳交，但其是否成功的關鍵點，仍有賴整體供應鏈的下游各使用者能否將正確完整的使用情境資訊回饋給註冊人。ECHA除了提供Chesar工具軟體外，也針對下游使用者提供之用途設計了使用地圖(use map)，始能以完整的暴露資訊，結合原本在IUCLID內的危害資訊產出風險評估與CSR。

三、芬蘭安全與化學局(Tukes)拜訪

此次行程一併拜訪Tukes，瞭解其組織業務與執行現況，該局為芬蘭掌管消費性商品及化學相關查核等主要之執法機關，最早創立於1995年，2011年進行重組，全局年度預算約為3,000萬歐元；人力為268人，其中學歷有14%為博士，碩士則占70%，其組織目標在於促進產品及工業的運作安全服務。Tukes一共分成4個主要部門，包括化學部門、工業部門、產品部門與認證部門，負責執行的法規包括REACH、化學物質分類、標示與包裝(classification, labelling and packaging, CLP)法規、殺生物劑

(Biocide)、清潔劑、植物保護產品(plant protection products, PPP)及化妝品等，共計8個歐盟法規(EU Regulation)、4個指令(Directive)與2個國家規定(National legislation)，除執法外，國際合作與協助芬蘭政府立法亦為其工作項目之一。

此次交流對象為化學部門，其年度人力為77人，在化學部門中又分成殺生物劑組、植物保護產品組、工業化學物質組及化學產品組。化學產品組年度人力為20人，過去一年共就約1,600個案件執行達420次的查核執法行動，執法的同時亦與芬蘭海關、勞安及環保相關主管機關合作，甚至與國防相關部門也有合作，而業者違法的樣態大多為沒有正確標示、安全資料表有違誤、產品資訊或登錄資訊不符，或違反禁限用法規等，大多案件均以建議與改善結案，亦有部分透過歐盟非食品類消費品快速通報系統(Rapid Alert System for dangerous non-food products, REPEX)行動通報。而在資訊提交的部分，芬蘭安全與化學局要求業者提交有在市場上或在芬蘭當地使用之化學物質產品，以安全資料表為主之資訊，目前總共約有3萬5,000個化學物質列為危害性化學物質，並有約5,000個化學物質從市場上淘汰，該局每年的查核行動除配合ECHA外，並利用該局自己擬定的風險評估方法，決定查核的對象物質與計畫。

由於Tukes肩負監督各化學相關工業產業界的重責大任，在組織定位上採同時與多個主管機關相連結的方式，並主要隸屬在就業暨經濟部下運作，而非環境部，而這樣的安排方式除保留了對於產業化學品相關實務之專業外，並對於整體國家發展與產業界有一定良好互動。原本的化學部門、工業部門與產品部門囊括了芬蘭境內所有化學相關的活動，近年更積極成立認證部門(Finnish Accreditation Service, FINAS)，主責認證與驗證，強化管理的架構。在交流過程中Tukes也曾提到，除按歐盟會員國一致性的REACH及相關制度外，依照各自國情與產業活動去加強或建構化學品管理，以芬蘭來說，林業為其國內佔出口總值約2成之重要產業，而植物保護產品與其林業又有密不可分的關係，因

此也成為管理上的重點項目。而以芬蘭的國家策略來說，除了與歐洲化學總署、聯合國、OECD等相關組織合作外，區域性（尤其在北歐）的國家合作對芬蘭來說更為重要。

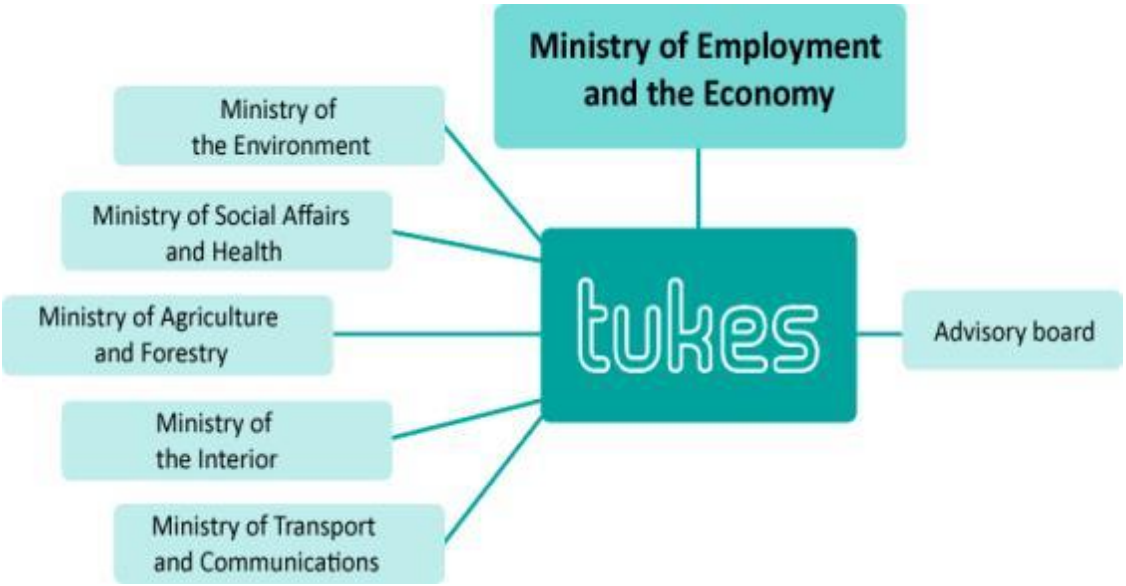

圖 13　芬蘭安全與化學局與其他機關關係圖

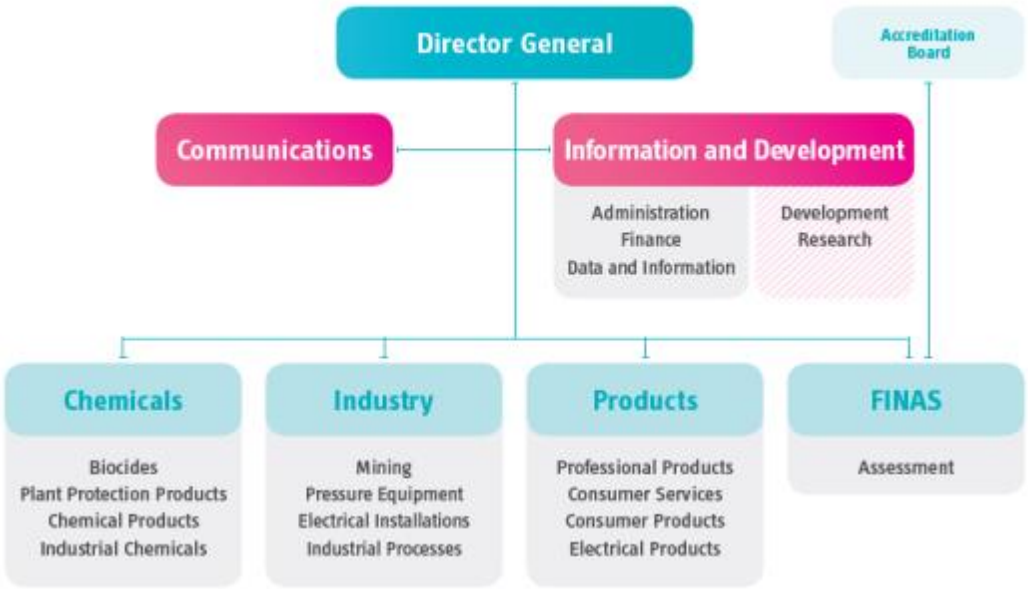

圖 14　芬蘭安全與化學局組織圖

Tukes也特別提到每個案件下所包含的物質、產品或銷售點可能都不只一個，因此單一執法案件背後所耗費的人物力不容小覷，且在芬蘭同樣也有中小企業知識與資源較不足，以致於未合乎規定的現象。而在芬蘭，除按原本歐盟各會員國已遵行的REACH制度註冊以外，針對化學物質產品本身首次上市及退出市場時，亦需要向Tukes提交以安全資料表為主之資訊與數量，這樣的申報資料可以讓官方掌握危害性化學品國內流通的趨勢，且因安全資料表內已包括危害分類等資訊，亦能從統計資料中瞭解評估相關化學品安全替代的展開優先性與成果。

表 2　芬蘭安全與化學局年度查核執法人力與約略案件數

Enforcement area	**Resources (persons)**	**Approx. # products or cases / tests**	**Approx. # inspections**
REACH & CLP & Detergents	7	1,300 / 100	250
Cosmetics	2	100 / 50	30
RoHS & batteries & accumulators	0.7	70 / 70	-
Package materials	0.2	70 / 60	-
Precious metals	3	10 / 5	120
Biocidal products	1	50 / 0	10
Plant protection products	2	40 / 20	10
Other	0.2	--	--

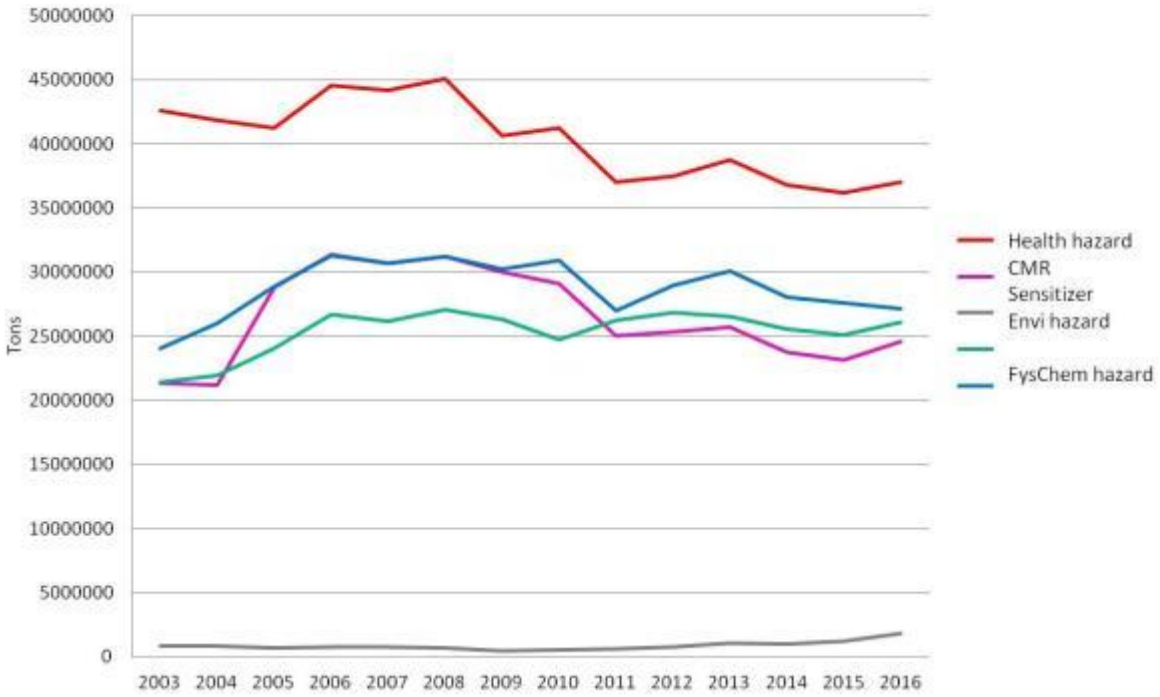

圖 15　芬蘭具危害性化學品歷年趨勢變化

而對於Tukes來說，人力亦相當有限，如何有效設定每年執法策略與目標更顯重要。Tukes在策略與目標的評估及設定方法上，與風險評估相當類似，導入矩陣式的分析方法，透過危害程度與發生或暴露機率，釐清風險高低再採取相對應的行動，並搭配國家政策方向設定優先順序，以二次的矩陣決定是否採取相關行動，值得注意的是，Tukes把能否增進相關專業知識也納入執法目標優先性決定的一環。

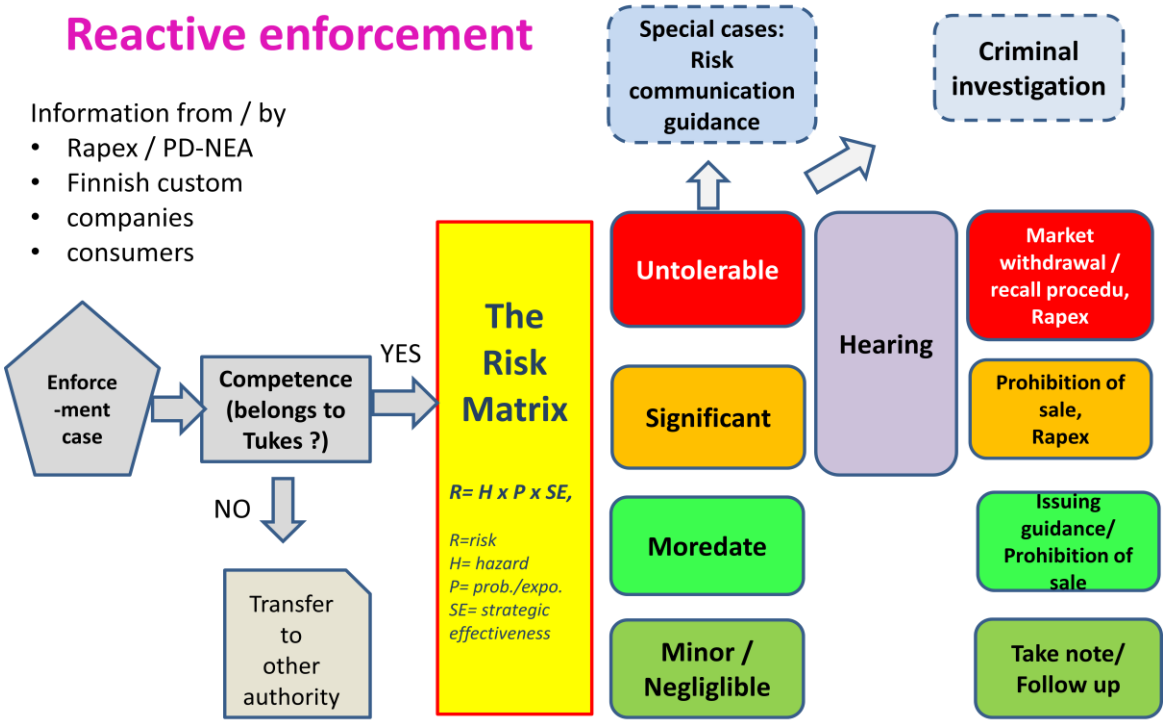

圖 16　芬蘭安全與化學局執法策略與目標計畫評估流程

Connection to the Tukes strategy		
Negligible 1	**Moderate** **2**	**Large** **3**
No clear connection to strategy Tukes action focuses only for single consumer / actor. Action does not increase the knowledge of Tukes	Involves strategic elements in some extent Tukes actions increase co-operation between other stakeholders or authorities Actions increase knowledge of Tukes organization. Small scale health/environment / economical impacts	**Strong strategy connection, ground of Tukes existence** **The effectivity can be measured by indicators.** **Tukes actions affects to large population / or environment compartments.** **High economical impacts.** **Political missions/tasks from Ministries**

圖 17　芬蘭安全與化學局執法目標優先性評分表

參、 心得及建議

2018 年為歐盟 REACH 分階段註冊最低數量級距（1-10 噸與 10-100 噸）資料繳交的最後期限，即便 ECHA 已有二次（2010 年與 2013 年）較高噸數級距註冊的階段經驗，但此次最後一階段註冊人以中小企業為主要組成的情形下，所面臨困難點逐漸偏向共同註冊，包括物質資訊交換論壇(SIEF)及與領導註冊人(Lead Registrant)間的溝通協調，而資料分享與各種因註冊所需費用與時間都成為中小企業投入註冊工作的障礙，技術條件與成本負擔是否能夠達到透明公平也成為業者間爭論的議題，針對這些較商業互動行為的部分，ECHA 依然拿捏適當的處理方式，把持不涉入過深的原則，給予適當的空間與建議。

透過本次參訪與會議參與，可以發現 ECHA 對於爭議議題與利害關係人間的互動，並不囿於規範或標準的解釋，而是能就學術與科學上的證據理由及政策目的與精神，展開較具彈性及個案性質的討論。此外，在跨部會間的交流亦是如此，如 ECHA 與歐洲食品安全局(European Food Safety Authority, EFSA)的互動，主要聚焦在科學技術，與化學物質學理上的溝通合作與意見交換，例如就雙酚 A 的風險評估上，ECHA 與 EFSA 即有不同之看法，需雙方專家進行相互討論，且因多屬學術上協調，雙方並無特定例行性會議作為平臺，多以電話聯繫或簡單會面即能達到目的。而作為歐盟化學物質相關管制之主管機關，ECHA 對於化學物質之評估與管理策略最終仍較具主導權。

ECHA 針對即將來到的 2018 年，除更新指引外，更為中小企業設計更便捷與更直覺的系統工具服務，包括 IUCLD 線上版及 Chesar 工具的更新。而 ECHA 的註冊資訊工具 IUCLID 與我國現行的登錄工具 Chemist (chemical information system and tool)相較起來，主要差異點在於對於測試終點填寫的自由度更佳，並留有更彈性的備註欄位供註冊人自由填寫，更符廣泛蒐集資訊的精神；內建方便引用的資料庫；強大的自動檢核偵錯設計，除了基本的必填欄位檢核，對於各欄位資料交互影響所生邏輯正確性亦有檢核功能；及對於複雜的共同註冊具備相關設計。這些優化措施都能作為我國登錄系統工具精進的參考方向。

REACH 的註冊制度與我國化學物質登錄相比，可繳交的資料與報告類型較為多樣化，在減少不必要的動物犧牲，保護動物權益的精神下，鼓勵以非脊椎動物的替代測試方法獲得數據，如交互比對法(Read-across)、定量構效關係(QSAR)，

與各種體外測試及證據權重(weight of evidence)等，我國在對於替代測試方法的知識與量能仍有相當發展空間。此外，我國為核准登錄制度，物質資料需經審查通過核准，與歐盟採取僅需收到資料，另再於後續篩選評估階段始進行部分物質資料細節審視與風險討論的作法，有相當大的差異性，亦一定程度限縮了廣泛蒐集資料的可能性。

而廣納利害關係人參與，與利害關係人溝通在國家政策執行扮演不可或缺的角色，加強與之共識，建立良好的互動管道與平臺，針對國內產業特性去規劃管理方式，分配管理資源，設定執法目標時，同樣導入風險評估的概念去釐清較重要且迫切的策略目標。同時，鑑於全球對於化學品規範重視的成長，發展將化學物質使用的負面效應最小化與具備永續性的管理目標，持續關注國際議題與動態積極交流合作，瞭解其他國家在制度架構設計上的安排與所面臨之挑戰，能從中參考學習，據以提升並建構符合國家未來發展及國際間共同努力之方向發展化學品管理制度。

肆、 附錄

附錄 1：行程

本次行程共計8天（包含往返交通時間），主要參與歐洲化學總署本（第12）屆利害關係人會議，並與歐洲化學總署專家進行交流討論及拜訪芬蘭安全與化學局，本屆利害關係人會議於4月4日至5日在位於芬蘭赫爾辛基的歐洲化學總署舉辦，相關行程如下。

日期	工作內容概要
106.04.01	搭機前往芬蘭赫爾辛基
106.04.02	抵達芬蘭赫爾辛基（經法國巴黎轉機）
106.04.03	歐洲化學總署拜訪交流
106.04.04	歐洲化學總署第 12 屆利害關係人會議（第 1 日） 註冊資訊工具訓練課程
106.04.05	歐洲化學總署第 12 屆利害關係人會議（第 2 日） 1. 朝向 REACH 2018 2. 成功註冊的案例 3. 在歐洲更安全的使用化學物質
106.04.06	芬蘭安全與化學局拜訪交流
106.04.07	1. 會議資料彙整 2. 搭機返回臺灣（經英國倫敦轉機）
106.04.08	返抵臺灣

附錄 2：第 12 屆利害關係人會議議程

ECHA
EUROPEAN CHEMICALS AGENCY

12th Stakeholders' Day

4-5 APRIL 2017
HELSINKI, FINLAND

Tuesday 4 April 2017

Training

Training on the IT tools for REACH registration

9.30-10.30	From zero to registration workshop
10.30-13.30	Chesar and QSAR Toolbox
14.30-17.30	IUCLID 6 and REACH-IT

One-to-one sessions

One-to-one sessions with ECHA experts are available on 4 April, when booked in advance.

Wednesday 5 April 2017

Plenary session 1

REACH 2018 - year to go

Chair: Andreas Herdina, Director of Cooperation, ECHA

08.00	REGISTRATION & MORNING COFFEE
09.00	OPENING Geert DANCET Executive Director, ECHA
09.10	SEVEN PHASES TO SUCCESSFUL REGISTRATION Christel MUSSET Director of Registration, ECHA
09.35	MISSING DATA? HOW TO GET IT Laurence HOFFSTADT Evaluation, ECHA
09.50	CLASSIFYING YOUR SUBSTANCE: DOS AND DON'TS Fabrice BROECKAERT Classification and Prioritisation, ECHA
10.05	HOW TO ENSURE A SUCCESSFUL SUBMISSION Mercedes VIÑAS Dossier Submission and PIC, ECHA
10.20	QUESTIONS & ANSWERS
11.00	COFFEE BREAK

Wednesday 5 April 2017

Plenary session 2

Case studies for successful registration

Chair: Christel Musset, Director of Registration, ECHA

11.30 CASE STUDY: SUBSTANCE IDENTITY
Mike PENMAN
Penman Consulting

11.45 CASE STUDY: APPLYING ALTERNATIVE METHODS
Wera TEUBNER
BASF Schweiz AG

12.00 CASE STUDY: COST AND DATA SHARING
Monica LOCATELLI
TEAM Mastery

12.15 CASE STUDY: NON-EU MANUFACTURERS
Rudolf STAAB
Only Representative Organisation

12.30 QUESTIONS & ANSWERS

13.15 LUNCH BREAK

Wednesday 5 April 2017

Plenary session 3

Using chemicals safer in Europe

Chair: Leena Ylä-Mononen, Director of Evaluation, ECHA

14.30 IMPROVING SUPPLY CHAIN COMMUNICATION: NOW TO 2020
Jack DE BRUIJN
Director of Risk Management, ECHA

14.50 HOW USE MAPS HELP IMPROVE SUPPLY CHAIN COMMUNICATION
Marten KOPS
A.I.S.E

15.10 CHEMICAL SAFETY REPORT AS COMPANY ASSET
Mike RASENBERG
Computational Assessment & Dissemination, ECHA

15.30 TIPS AND TOOLS FOR CHEMICAL SAFETY ASSESSMENT
Dirk SCHWARTZ
Bruno Bock Thiochemicals

15.50 QUESTIONS & ANSWERS

16.30 CLOSING REMARKS
Jukka MALM
Deputy Executive Director, ECHA

16.45 - 18.30
MEET THE ECHA STAFF

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附錄 3：第 12 屆利害關係人會議講者資料

Plenary session 1

Opening

Geert DANCET
Executive Director, ECHA

Programme

09.00
Opening

Geert Dancet became the first elected Executive Director of the European Chemicals Agency (ECHA) in January 2008. Under his leadership, the Agency successfully managed all regulatory processes of the REACH and CLP regulations. ECHA has become one of the largesize regulatory agencies of the EU with over 500 staff members in charge of the EU chemicals legislations, including the new Biocidal Products and PIC regulations. His mandate was renewed in 2012 andwill end on 31 December 2017.

The Commission nominated him as interim Executive Director in January 2007 in order to set up the Agency in Helsinki as from 1 June 2007.

From 2004 to 2007 he was the Head of the REACH Unit in the European Commission's Directorate General for Enterprise and Industry. The unit was co-responsible for taking the REACH proposal through the regulatory process in the Council and the European Parliament as well as for developing and coordinating the REACH implementation strategy, which included the preparations for the new Chemicals Agency.

He first joined the European Commission in 1986 and worked for most of his Commission career in the competition policy field. Prior to working for the European Commission, Mr Dancet enjoyed a brief academic career in the University of Leuven (Belgium) and was programme coordinator for the United Nations Industrial Development Organisation (UNIDO) in Colombia.

He studied economics, econometrics and philosophy at the University of Leuven, Belgium. Mr Dancet is married with four children.

Plenary session 1

REACH 2018 – Issues and solutions

Christel MUSSET

Director of Registration, ECHA

Programme

09.10
REACH 2018 – Issues and solutions

Christel Musset joined the European Chemicals Agency (ECHA) on 1 September 2007 and is currently responsible for all activities related to the registration process under REACH – this also comprises data sharing and dissemination and the coordination of IT systems to support these activities, in particular REACH-IT and IUCLID.

Before joining the Agency she worked in the European Commission, at the European Chemicals Bureau (ECB) of the Joint Research Centre (JRC) in Ispra, where she coordinated the development of IT systems for REACH. Prior to joining the European Commission, she held several positions in the private sector, first managing large-scale IT projects and then as a director of Sales and Marketing.

Ms Musset studied Physics and Computer science and is a postgraduate in Business and Administration.

Ms Musset is in charge of the directorate for Registration and she is of French nationality.

Laurence HOFFSTADT

Evaluation, ECHA

Programme

09.35
Missing data? How to get it

Laurence Hoffstadt is a pharmaceutical doctor and holds a PhD in Toxicology.

After her studies on in vitro eye irritation at Janssen Pharmaceutica (Belgium) and Johnson & Johnson (USA) she pursued her post-doctoral experience in a clinical research organisation (CRO) in England. She then followed her husband, who started a research project in Benin (West Africa) and worked in a pharmaceutical company producing generic medication for the West African market.

After returning to Europe, she joined Brussels-based ExxonMobil Petroleum & Chemical. She was involved in numerous toxicological aspects relevant to EU legislation (REACH, food safety, alternatives to animal testing) interacting also with external partners (EPAA, ECETOC). She then seized the opportunity to work for the European Chemicals Agency (ECHA) in Helsinki.

Her initial tasks at ECHA were to develop the implementation of the data sharing provisions and the support to SIEFs. She currently contributes to the evaluation of registration dossiers and the development of supporting material for the Iregistrants of the last registration deadline.

Fabrice Broeckaert has a PhD in industrial toxicology from the Catholic University of Louvain in Belgium. Since 2011, he has held the position of senior scientific officer within the unit of classification and prioritisation in ECHA. He is in charge of the coordination of CLP classification dossiers.

Before joining ECHA, he worked 12 years in different industrial sectors as regulatory and registration toxicologist. He is a European Registered Toxicologist and the author of several peer-reviewed publications and science book chapters.

Fabrice BROECKAERT

Classification and Prioritisation, ECHA

Programme

09.50
Classifying your substance: dos and don'ts

Mercedes Viñas joined the European Chemicals Agency (ECHA) in June 2013. She is currently heading the unit Dossier submission and PIC in the Registration Directorate of ECHA.

She oversees ECHA's activities on the submission and processing of dossiers including the 2018 registration deadline, and the related support to industry. Her unit is also in charge of the implementation of the Regulation on Prior Informed Consent (PIC) and the submission of information to the appointed bodies and poison centres under the CLP Regulation.

Mercedes is a Chemical Engineer with a postgraduate in European legislation. She has been working on the implementation of the REACH Regulation since 2004 in different positions in the European Commission and industry associations.

Mercedes VIÑAS

Dossier Submission and PIC, ECHA

Programme

10.05
Submitting successfully: tips from ECHA

Plenary session 2

Case studies for successful registration

Mike PENMAN

Penman Consulting

Programme

11.30

Case study: substance identity

Mike Penman has 40 years' experience in managing toxicology, regulatory affairs and information technology on a global basis.

He worked for ICI (Central Toxicology Laboratory and Chemicals & Polymers business) in the UK, then later in the US and Europe for ExxonMobil. Externally, has chaired and managed a number of scientific and regulatory groups. He was involved in the initial development of IUCLID and was an original author of the ECETOC TRA exposure model. He chaired the Reach Implementation Project responsible for the initial guidance on Information Requirements. During this time, he was awarded a UK civil honour for "Services to Environmental Safety".

In May 2007, he founded Penman Consulting (now 25 + staff around Europe mainly in Belgium and the UK) providing managed service solutions to industry and Consortia on chemical regulation, toxicology and environmental sciences. These services include Technical (toxicology, environment and exposure issues) Product Stewardship, and Regulatory activities.

The business has been central in managing major project and consortia under REACH, developing hundreds of registrations for highly complex substances, subsequently developing and managing complex testing strategies to meet the increasingly stringent requirements of REACH.

Dr Wera TEUBNER

BASF Schweiz AG

Programme

11.45

Case study: applying alternative methods

Dr. Teubner is a EUROTOX-registered toxicologist holding the position of a regulatory toxicologist in the product safety department of BASF Switzerland. Her work includes the human health hazard and risk assessment of industrial chemicals with special focus on (Q)SAR modeling and the application of in-vitro methods.

She previously worked as a toxicologist for Ciba Expert Services and as a post-doc in the department of toxicology of human nutrition at the University of Potsdam. She received her diploma in biochemistry from the university of Hannover, Germany and did her phD at the German Institute of Human Nutrition in Bergholz-Rehbrücke, Germany.

Monica LOCATELLI

REACH Mastery

Programme

12.00

Case study: cost and data sharing

After a degree in chemistry and ten years in Chemical Industry, first in R&D then in the Regulatory field, she specialised in toxicology applied to risk assessment and has been working in regulatory and implementation of REACH regulation since 2001, when REACH was still a proposal.

She specialised in Risk Assessment and she participated in several working groups for technical discussions and safety reports with ECHA (European Chemical Agency), EFSA (European Feed and Food Chemical Agency) EPA (Environmental Protection Agency) and the pharmaceutical industry. She participated from 2008 as active member to the main European Projects focused on exposure scenarios and Environmental Risk Assessment like the Chesar Consultation Group (ECHA) and the ENES network (ECHA).

Monica Locatelli founded REACH mastery in 2008 as a REACH specialised consultancy company.

The group has this year changed the name in TEAM mastery, counts of 16 people specialised in the different areas of toxicology, eco-toxicology, modelling and in-vitro testing. It gained a great experience in organising projects, contracting and monitoring toxicological and eco-toxicological studies for the registration of hundreds chemicals under REACH Regulation, Authorisation dossiers, Biocidal Active Substances and Products, pharmaceuticals and assessment of Feed and Food additives and Cosmetics.

The last newborn division is dealing with Plant Protection Products and Fertilizers.

Dr Rudolf STAAB

Only Representative Organisation

Programme

12.15

Case study: non-eu manufacturers

Rudolf Staab holds a PhD in Inorganic Chemistry from the University of Saarbrücken, Germany. He spent 25 years in the chemical industry thereof 14 years in top management positions at Hoechst and Clariant. Since 2004 he is Partner at ChemAdvice GmbH a top level consultancy company focused on business transactions.

On request from his network in the chemical industry of the USA he founded REACh ChemAdvice GmbH in 2007 to offer Only Representative Service to Non-EU manufacturers worldwide. As a founding member of the Only Representative Organisation, the trade association for ORs, he serves as Vice Secretary since 6 years and is co-author of the Best Practice Guide for ORs and other interested parties.

Plenary session 3

Using chemicals safer in Europe

Jack DE BRUIJN

Director of Risk Management, ECHA

Programme

14.30

Improving supply chain communication: now to 2020

Jack de Bruijn started working at the European Chemicals Agency (ECHA) right from the start in September 2007. He is currently heading the Risk Management Directorate that is responsible for identifying and implementing the authorisation and restrictions processes under REACH as well as managing the classification related tasks resulting from the CLP Regulation. Since the beginning of 2014 the Directorate also manages and coordinates ECHA's scientific evaluations and assessments under the Biocidal Products Regulations (BPR).

Before joining the Agency Mr de Bruijn worked at the European Chemicals Bureau (ECB) of the Joint Research Centre (JRC) in Ispra where he coordinated the development of the guidance documents for REACH. Before joining the ECB he worked for many years for the Dutch national authorities in the area of regulatory risk assessment of chemicals.

Mr de Bruijn is chemist by training and has a PhD in environmental toxicology.

Marten KOPS

A.I.S.E

Programme

14.50

How use maps help improve supply chain communication

Marten Kops is Manager Scientific & Regulatory Affairs at NVZ, the Dutch Detergents Association. As chairman of the REACH Implementation Working Group of A.I.S.E., the International Association for Soaps, Detergents and Maintenance Products, he has been a key contributor in the development of the A.I.S.E. REACH tools like use maps and Safe Use of Mixtures Information (SUMIs). Through his efforts at a national level, the professional cleaning industry in The Netherlands is becoming a key example of how REACH-generated information can truly lead to safer workplaces at the end of the supply chain.

At NVZ Mr. Kops is responsible for several regulatory dossiers like REACH, CLP and the Occupational Health & Safety legislation. He holds a master's degree in toxicology and has over 7 years of experience with chemical regulatory affairs.

Dr Dirk Schwartz is an European-registered toxicologist with an academic background in chemistry and molecular biology. He switched from the pharmaceutical industry to the chemical industry in November 2010 to became Head of Product Safety & Regulations at Bruno Bock Thiochemicals.

Besides REACH he is in charge of coordinating all activities related to chemical inventories and chemical regulations worldwide. Dirk Schwartz is married, has two children and lives in Hamburg, Germany.

Dr. Dirk SCHWARTZ

Bruno Bock Thiochemicals

Programme

15.10
Tips and tools for chemical safety reports

Mike Rasenberg has over 17 years of professional experience working in the field of chemical regulatory affairs with both governmental bodies and enterprises.

Mr Rasenberg is Head of Unit for Computational Assessment and Dissemination at the European Chemicals Agency (ECHA) since January 2011. Before this, Mr Rasenberg worked in the area of international chemicals management, with the European Commission, Chemical Industry, industry associations and as a consultant.

Mike RASENBERG

Computational Assessment & Dissemination, ECHA

Programme

15.30
Chemical safety report as company asset

Jukka MALM

Deputy Executive Director, ECHA

Programme

16.30

Closing remarks

Jukka Malm joined the European Chemicals Agency (ECHA) in September 2008 as the Director of Assessment with the main responsibility to build up the processes of evaluation and risk management.

Since 2011 Mr Malm is leading the directorate of Regulatory Affairs, and was appointed as Deputy Executive Director in January 2014. He is responsible for the work of Scientific Committees of ECHA and for the Legal Affairs unit. In addition, he is coordinating the scientific activities of the agency.

Mr Malm has been working in the field of chemicals legislation for over 25 years and has been involved in a wide range of activities related to the risk assessment and risk management of chemicals at the national, EU, and global level. Prior to working at the Agency he worked as the Director of Expert Services at the Finnish Environment Institute and was also the first chairman of the Management Board of ECHA.

He holds a Master's degree in Agriculture and Forestry, specialising in Environmental Protection. Mr Malm is Finnish.

附錄 4：資訊工具基礎訓練課程參考講義

Stakeholders' day REACH 2017 – 4th of April – IT Tools training

ECHA Cloud Services and IUCLID

1. Go to the ECHA Cloud Service page
2. Login with the Username and password provided on the small piece of paper
3. In the Cloud, subscribe to the IUCLID Cloud Trial service by approving the Terms and conditions. Please note that this will take over a minute. If you are idle for more than 15 minutes, the re-activation will take around the same time
4. Access the service to enter the IUCLID Cloud application
5. Have a look at the user journey to learn what you can do in the Cloud at the moment
6. Navigate to the available substance and look how the reading of the dataset has been implemented

7. Download the IUCLID 6 substance dataset from the training materials for your session and import it into the cloud
8. Check in your list of substances that the newly imported dataset is there and browse through its content
9. Access section '1.4 Analytical information' and select 'Edit using the Cloud Client'. This will launch the IUCLID Client which will be used for the exercise
10. Launch the Validation Assistant in order to check if the content of the dataset is correct for a REACH inquiry
11. Fix the (three) issues identified
12. Create a REACH inquiry dossier for the substance dataset and check the dossier one more time with the Validation Assistant
13. Export your dossier to your Desktop

14.Continue with...

Stakeholders' Day 4-5 April 2017

REACH-IT Online exercise

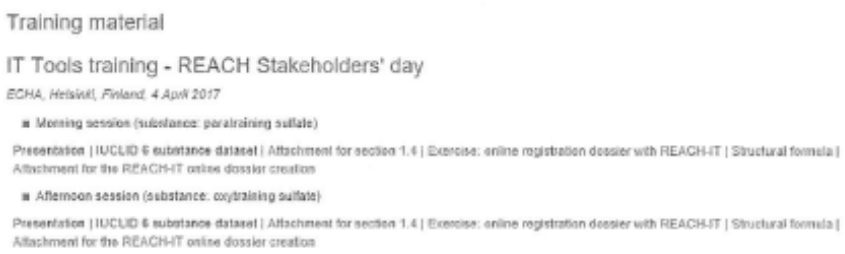
Login to the test environment:

Link to the test environment can be found on your desktop.

Username and password is provided separately.

Note 1: You will need to attach some files during the online dossier creation. You can attach the same file during the exercise. Download it from the IUCLID 6 website (link available in the desktop) and save it on your desktop.

The structure of the substance is also available for you to download.


Training material

IT Tools training - REACH Stakeholders' day

ECHA, Helsinki, Finland, 4 April 2017

- Morning session (substance: paratraining sulfate)

Presentation | IUCLID 6 substance dataset | Attachment for section 1.4 | Exercise: online registration dossier with REACH-IT | Structural formula | Attachment for the REACH-IT online dossier creation

- Afternoon session (substance: oxytraining sulfate)

Presentation | IUCLID 6 substance dataset | Attachment for section 1.4 | Exercise: online registration dossier with REACH-IT | Structural formula | Attachment for the REACH-IT online dossier creation

Objective of the exercise:

Create an online dossier in REACH-IT (1-10 tonnes/year) for the substance 'Paratraing sulfate' (EC 944-653-8).

Tips:

Use the help by clicking on the help icon or raise your hand for help.

Use the 'Save' button!

Steps towards a successful online submission:

1. After you receive the inquiry reference number, search for the joint submission that has been created for 'Paratraing sulfate' (EC 944-653-8) and join to it. The token is available in the supplementary information section of the joint submission.

2. Create and submit the dossier online following the defined steps. Launch the wizard from the joint submission page, clicking on the '*Create and Submit online*' button (The system will invite you to start creating your substance in the IUCLID environment):

    a. **Main constituents:** the substance is a well-defined substance. Edit the substance, which is a monoconstituent with NaC12H25SO4 as molecular formula with a molecular weight of 288.372 g/mol. You can download the structural formula directly from the IUCLID6 website (save it in your desktop before uploading it).

    b. **Substance identification:** review this information. Do you see the structural formula and the molecular weight?

    c. **Trade name and other identifiers:** You are planning to use 'Pure P-Sulfate' as the trade name.
    You have **quantified** and **identified** your substance with the help of a gas chromatography (GC). In both cases you will provide the results of your test by attaching the file that can be downloaded from the IUCLID 6 website ('Attachment for the REACH-IT online dossier creation').

    d. **Substance composition:** You are registering solid paratraining sulfate on a concentration range of 98% to 99 %. Since we are working with a monoconstituent, the main constituent is the same. The main impurity is water 1-2% (EC 231-791-2).

    e. **Supply chain:** You are a manufacturer.

    For that reason you need to create one production site. Use your imagination when creating one.

f. **Administrative information:** your phase-in substance will be registered for a tonnage band between 1 to 10 tonnes/year.

g. **C&L inventory:** Although members can always indicate their own C&L in this case **you agree** with the C&L provided by the lead.

Members that do not agree with the C&L provided by the lead need to provide a justification for opting-out and provide their own information on the claissification and labelling.

h. **Uses:**

You are a manufacture of the substance therefore you need to fill the Manufacture section.

- At least one contributing activity / technique for the environment and one contributing activity / technique for workers must be provided.
- Each contributing activity must be described with the appropriate 'Environmental release category' and 'Process category' codes, or an 'other:' category must be filled in.
- **The manufacture uses identified are indicated in the table below.**

Field name	Input	Help
Manufacture name	Manufacture	
Contributing activity/technique for the environment		Provide first the name, and then search for the most relevant ERC (Environmment Release Category). In this case ERC1
Name of activity / technique	Manufacture in contained system, no water involved	
Environmental release category (ERC)	ERC1	

Contributing activity/technique for workers		Provide first the name, and then search for the most relevant PROC (Process Category)
Name of activity / technique	Closed manufacturing process	
Process category (PROC)	PROC1	
Contributing activity/technique for workers		Provide first the name, and then search for the most relevant PROC (Process Category)
Name of activity / technique	Transfer of substance from the vessel into smaller containers (dedicated facility)	
Process category (PROC)	PROC8b	
Contributing activity/technique for workers		Provide first the name, and then search for the most relevant PROC (Process Category)
Name of activity / technique	Equipment cleaning and maintenance	
Process category (PROC)	PROC28	
Sites	Select the manufacturing site created earlier in the online wizard	

Additionally, as you can read on the page at least one use other than manufacture should be provided or a justification for no uses should be specified. In this case you will be filling the field of the **uses at industrial site**.

- The fields 'Technical function of the substance during use' and 'Subsequent service life relevant to this use' must be filled in.
- In addition, at least one contributing activity / technique for the environment and one contributing activity / technique for workers must be provided.

- Each contributing activity must be described with the appropriate 'Environmental release category' and 'Process category' codes, or an 'other:' category must be filled in.
- **The uses at industrial site identified are indicated in the table below.**

Field name	Input	Help
Use name	Use of vehicle cleaning product	
Further description of use	Spraying and rinsing of cleaning product at car manufacturing lines (largely automated process – mainly open – ambient temperature)	
Contributing activity / technique for the environment		Provide first the name, and then search for the most relevant ERC (Environmment Release Category)
Name of activity / technique	Automated water based washing of large articles – indoor use	
Environmental release category (ERC)	ERC4	
Contributing activity / technique for workers		Provide first the name, and then search for the most relevant PROC (Process Category)
Name of activity / technique	Transfer of products with manual coupling/decoupling	
Process category (PROC)	PROC8b	
Contributing activity / technique for workers		Provide first the name, and then search for the most relevant PROC (Process Category)
Name of activity / technique	Spraying and rinsing of a diluted cleaning product (automated process; open systems)	

Process category (PROC)	PROC7	
Product category	PC35	
Sector of end use	SU17	
Technical function of the substance during use	Surfactant	You can start typing to easily find the technical function
Subsequent service life relevant for this use	No	

'Chapter R.12: Use description' of the Guidance on Information Requirements and Chemical Safety Assessment will help you to fill your uses in the future: http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

i. **Uses advised against:** Not provided

j. **Use information:**

It is adviseable to provide the estimated quantities of all the available years, but at least the information of the last three years should be provided for phase-in substances.

Year 2014: 5 tonnes manufactured
Year 2015: 7 tonnes manufactured
Year 2016: 9 tonnes manufactured

k. **Assessment reports:** You agreed that they would be provided by the lead registrant.

l. **Confidentiality claims:** This is up to you, but remember that in case you claim confidential certain parts of your dossier you need to provide a proper justification that will be then assessed by ECHA. An additional fee will be issued when claiming certain parts of your dossier confidential.

m. **Dossier preview:** Review the information that you have provided

n. **Submission to REACH-IT:** Submit your dossier.

3. Follow up the progress of your dossier:
   a. Find the invoice that needs to be paid. Inform us so we complete the payment.
   b. Get your registration number.

Congratulations! You have just successfully completed your first online dossier!

ECHA
EUROPEAN CHEMICALS AGENCY

The NEW OECD QSAR Toolbox version 4.0

The new OECD QSAR Toolbox v.4 simplifies the correct use of non-test methods. Users with a sufficient understanding of (eco)toxicology can now focus on the content while being guided in their choices by the software

More user friendly

Toolbox v.4 highlights with colours the profilers, metabolic simulators and databases that are relevant for the endpoint you are working on.

Relevant profilers

Profilers are considered "Suitable" and are coloured in green if they have been developed using data for the endpoint of interest. "Plausible" profilers (in orange) are also somehow related to the endpoint of interest (e.g. the functional groups profilers, which are useful for finding structural analogues).

Relevant databases

Databases containing data for the endpoint of interest are coloured in green.

Relevant metabolic and transformation simulators

Metabolic and transformation simulators related to the endpoint of interest are coloured with the same logic of the profilers.

Improved reports

Reports have been completely revised to make the most important information readily accessible and understandable. The possibility to export the data matrix to Excel simplifies the preparation of read-across and category documentations.

Prediction report

Target information and prediction summary are all available in the first page of the report. Details are described from the second page onwards, starting from the most relevant ones.

Data matrix in Excel format

The preparation of the data matrix listing structures and properties of the category members has always been a time consuming operation. Now, you can automatically generate and customise such a matrix for any prediction run with the Toolbox.

Guided predictions

The automated and standardised workflows guide you in the prediction of selected endpoints straight after the input. In Toolbox v 4.0 these workflows are available for skin sensitisation and aquatic short-term toxicity.

Automated workflow: input the chemical and obtain a prediction

Input the chemical and select the workflow for the endpoint you want to predict.

Standardised workflow: input the chemical and be guided in each step

You can choose among the options proposed by the Toolbox.

Manual prediction: as in Toolbox v.3, it is all up to you

If you are familiar with the previous version, you can still use the Toolbox in the classical way. Nevertheless, you can now select an endpoint and activate colour coding for getting help in the selection of databases and profilers.

How to run the new workflows?

1. Input your target
2. Go to data gap filling
3. Select automated or standardised workflow
4. Follow the wizard

And much more...
www.qsartoolbox.org

echa.europa.eu

European Chemicals Agency, Annankatu 18, FI-00121 Helsinki, Finland

ECHA OECD oasis
QSAR TOOLBOX

What is the OECD QSAR Toolbox?

The QSAR Toolbox is a decision-support tool to find experimental data for chemicals, group substances into categories based on chemical and mechanistic similarity, and predict substance properties without testing

Key elements:

1. Modules
2. Target chemical
3. Analogues
4. Endpoint tree
5. Data Matrix
6. Document tree
7. Profilers

What can you do with the Toolbox?

Profiling – get a summary of relevant properties for your substance(s). The profilers are used as criteria to find analogues, but they are also useful for preliminary screening or prioritisation of substances.

Account for metabolism – collect the transformation products observed or predicted for your substance. Sometimes, metabolites and degradation products are cause of toxicity

Find data – retrieve all experimental information available in the Toolbox for your substance(s). The Toolbox also includes details and references

Grouping – find analogues for your substance and the available experimental data for them. It is useful for identifying analogues and data gaps

Predict – fill a data gap for your substance by using trend analysis, read-across and existing QSAR models

Over two million data points!

The Toolbox gathers a large number of publicly available databases

Database Content	Chemicals	Data points
Physical Chemical	45 238	177 258
Environmental Fate and Transport	9 446	97 469
Ecotoxicological	17 849	856 473
Human Health	30 447	912 687
Total number	**79 204**	**2 043 887**

The terminology

Definitions in the QSAR Toolbox context:

NON-TEST METHODS – methods that do not require performing a new experiment (QSAR, read-across, trend analysis) to fill a data gap

TARGET CHEMICAL – chemical of interest

MODULE – the Toolbox consists of six modules, each of them performing some specific actions useful for data gap filling

PROFILER – algorithm (rule set) for the identification of specific features of chemicals. Several types of profilers are available, such as structural (e.g. organic functional groups) and mechanistic (e.g. Protein binding by OECD) ones

CATEGORY – "group" of substances. Usually it consists of a target chemical and its analogues gathered according to the selected profilers (e.g. some functional groups)

ENDPOINT TREE – The Toolbox organises endpoints in a branched scheme, from a general level (Physical Chemical properties, Environmental Fate and transport, Ecotoxicology, Human health hazard) to a more specific one (e.g. EC3 in LLNA test under Human health hazard-Skin sensitization). The levels can be re-arranged by the user

DATA MATRIX – Table reporting substances, data and profiler outcomes. The first row shows the structures. Each chemical defines a column

WORKFLOW – the use, in combination, of the different modules (e.g. prediction workflow: from input to report)

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QSAR TOOLBOX