

Chemia 2008
REACH-pred-registracia
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REACH IT & IUCLID 5 najnovšie informácie

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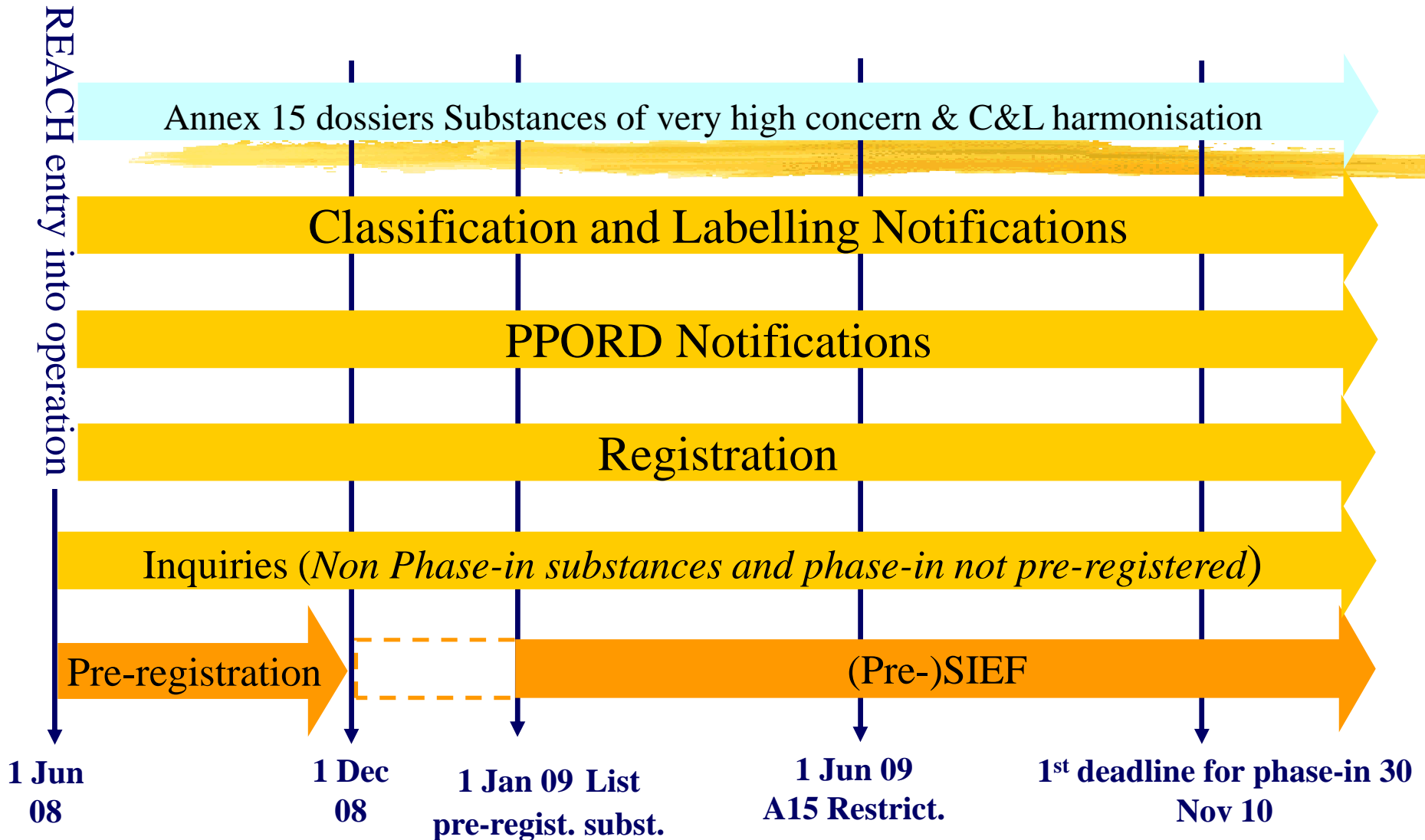
Helsinki, Finland

Established
1 June 2007

Operational
1 June 2008



What starts on 1 June 2008



Go Live

- REACH-IT went live on 31 May 2008 at 21:15
- The first company was signed up after 15 minutes
- on 1 June, 1286 pre-registrations were submitted
- on 4 June, Norway, Iceland and Liechtenstein were added to the system
- on 22 July, release 1.1 of REACH-IT was successfully published



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http://echa.europa.eu/pre-registration_en.asp
http://echa.europa.eu/pre-registration_de.asp



The screenshot shows the ECHA website in a Microsoft Internet Explorer browser window. The browser's address bar displays the URL http://echa.europa.eu/pre-registration_en.asp. The website header features the ECHA logo and the text 'European Chemicals Agency'. A navigation menu on the left includes links for HOME, PRE-REGISTRATION, REACH, CLASSIFICATION, PRESS & EVENTS, ABOUT, and WORKING WITH US. The main content area is titled 'Pre-register to benefit from extended deadlines' and contains the following text:

REACH, the new EU chemicals regulation, requires that chemical **substances** on their own, in preparations and those which are intentionally released from articles have to be registered to the European Chemicals Agency (ECHA). The regulation applies to substances manufactured in, or imported to the EU in annual quantities of 1 tonne or more per company, unless the regulation indicates otherwise.

The obligation to register applies from 1 June 2008. The chemicals currently on the EU market which meet the definition of **phase-in substances** should be pre-registered between 1 June and 1 December 2008. Companies who pre-register their substances can benefit from extended registration deadlines. The deadline depends on the tonnage band and the hazardous properties of the substance. The staggered deadlines are:

- 30 November 2010,
- 31 May 2013 or
- 31 May 2018

Pre-registration is free and simple

Pre-registration requires only limited data and there is no fee associated to it. A pre-registration file for a substance consists of:

- **Substance Identity:** EINECS number, CAS numbers and names of the substance
- envisaged **deadline** and tonnage band for the registration
- name and contact information of a **Contact person** or **Third party Representative** who will act as the contact point in data sharing

A pre-registrant should also provide when applicable **substance identification of any relevant substances** which may facilitate the risk assessment and data sharing of the substance

From an inventory to a registration

The process from knowing your REACH roles and substances to registration has several steps. The roles are explained in the **Actors** section of the **About REACH** web page on the **Guidance website**. The seven steps are presented in the graph below. Each of the steps has its own web page. The preparation, company account creation and submission of a pre-registration file steps can be carried out by different methods. All the potential options are explained first on the generic page for the step. More details are given on the option specific page.

At the bottom of the page, a horizontal flowchart shows the registration process steps: 'Know your' (yellow), '+ Manually' (yellow), 'REACH-IT' (green), 'SIEF' (yellow), and 'Joint Submission' (green).

Vorregistrierung - Leitfaden



REACH Industry Preparation Letter No 8

August updated version of April's Letter

Pre-registration Guidance



**Lassen Sie Ihre chemischen Stoffe
vorregistrieren, um REACH-konform im
Geschäft zu bleiben!**

Falls Sie Chemikalien herstellen, importieren oder verwenden oder Erzeugnisse importieren, ist die Vorregistrierungsfrist vom 1. Juni – 1. Dezember 2008 eine kritische Zeit für Ihre Geschäfte.

Pred-registracia



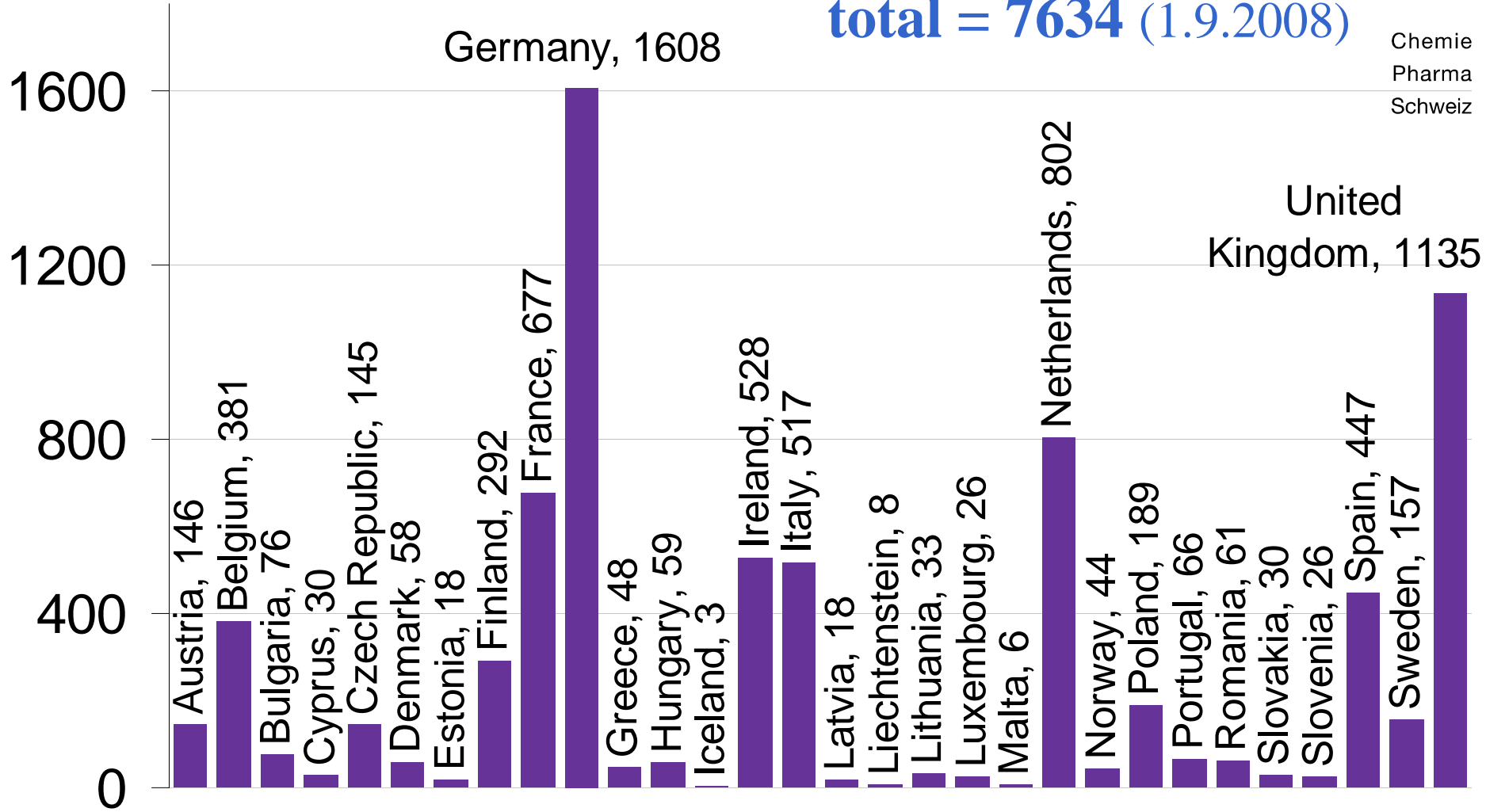
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- Pocas prvych 3 mesiacov sa registrovalo 7634 Legal entities (LE) (zo vsetkych 27 clenских krajín a z EEA). De: 1608 (21%), UK 1135 (15%), NL: 802(10%), **SK 30**
- Do 1.9.2008 bolo podanych totalne 206 185 pred-registracii, z toho UK 60% , De 15% , I 6%
- momentalne je denne asi 3000 pred-registracii
- stale este je asi 40 % podanych manualne (t.z. jednotlivé latky)
- Bulk –pred-registracia: z totalne 1791 bulk-files 198 (11%) nefungovalo. Najcastejsie kvôli XML-chybám alebo nespravnej adrese Third Party Representative
- Po prenesení dát (upload) trvá priemerne 6 hodín, kým príde spätná zpráva. To je nutné kvôli vírusovej kontrole (virus check).
- 97 % pred-reigistrovaných látok je v zozname EINECS
2 % majú len CAS číslo
1% len s menom látky.

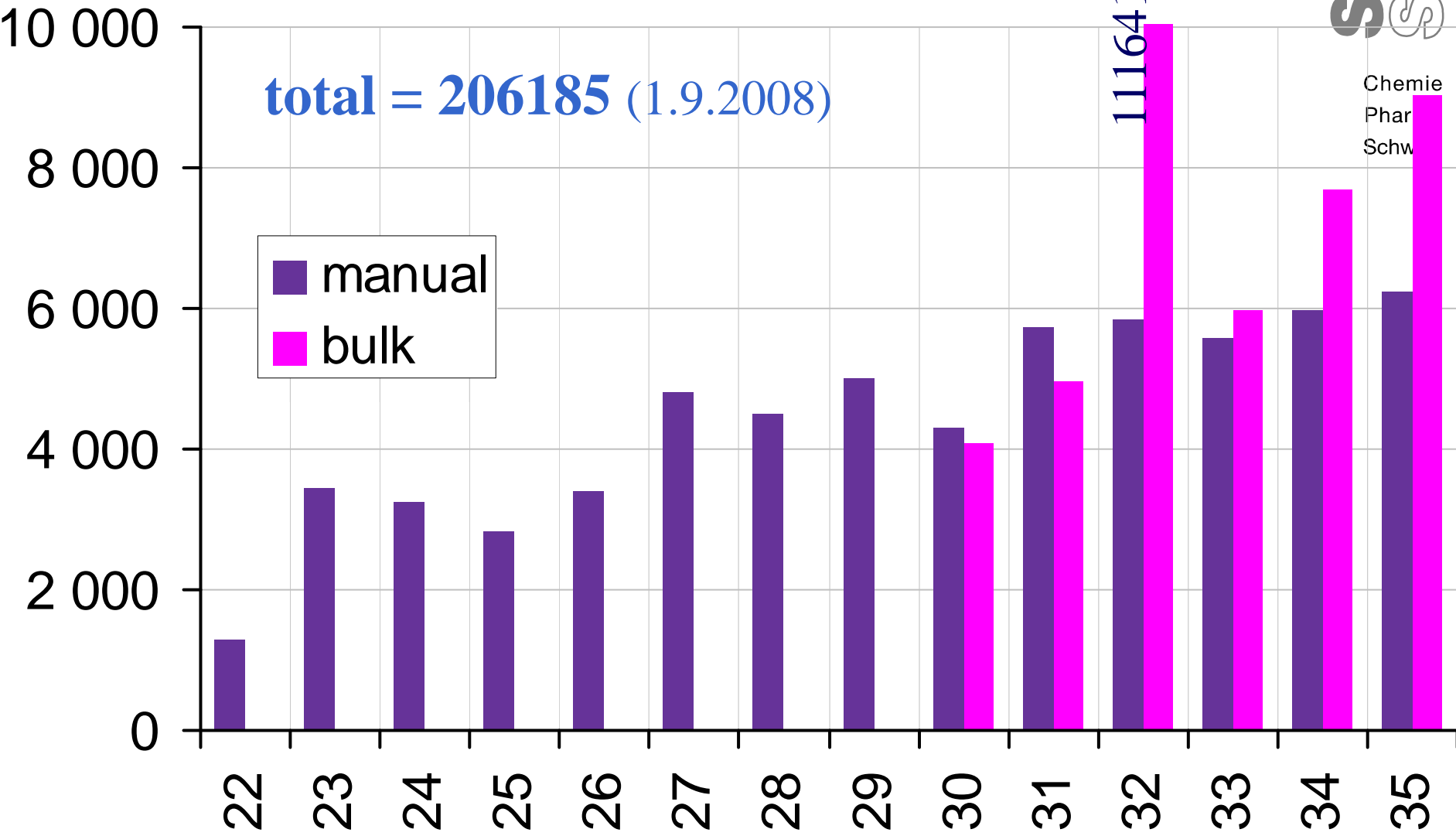
Legal entities signed up

total = 7634 (1.9.2008)

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Pre-registrations per week



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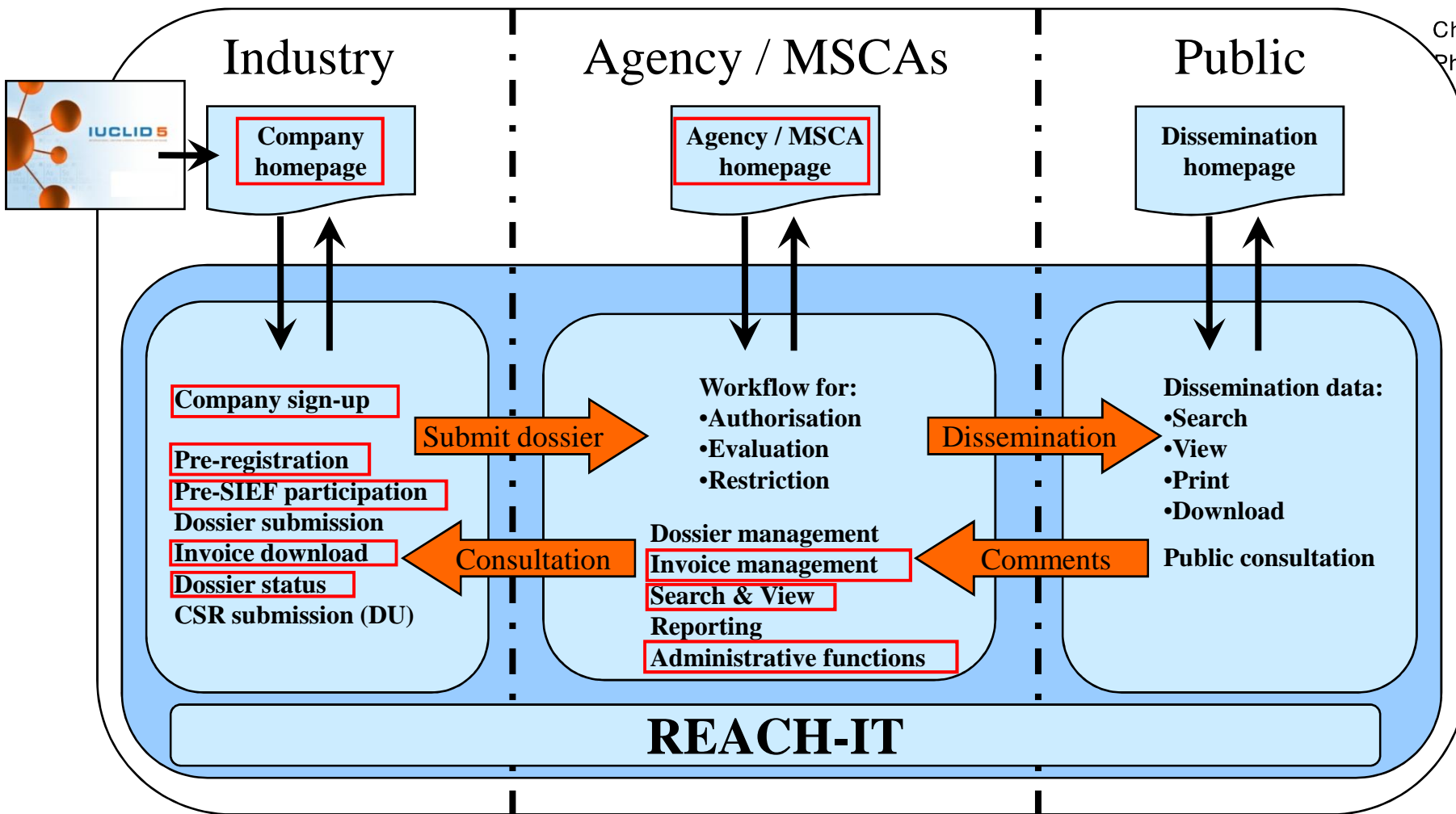
Pre-registration options (1)

- On-line in the REACH-IT portal
- Single Upload to the REACH-IT portal
 - XML file created with the IUCLID5 Pre-registration Plug-in
- Bulk Upload to the REACH-IT portal
 - XML file created with the IUCLID5 Pre-registration Plug-in
 - OR
 - XML file created with the Cefic/CONCAWE Excel Tool
- More information
http://echa.europa.eu/pre-registration_en.asp

REACH-IT functionality

- Bulk pre-registration
 - Limited to substances (incl. similar substances) and constituents with EC numbers).
 - Max. **500 substances** per bulk pre-registration file.
 - Bulk file must be compliant with the XML format published on the IUCLID website.
- **Odporucanie:**
najviac 200 latok naraz. Vyhodnejšie je používať balíky medzi 50 -100 latkami.

System Overview (1.0)



REACH-IT functionality (1.0)

- Industry functionality:
 - Company and Third party representative sign-up (including LEO upload and download)
 - User management (including roles)
 - Online pre-registration
 - Pre-SIEF formation (with XML download)
 - Search of submitted data (pre-registrations)
 - Internal REACH-IT messaging system (information from REACH-IT to industry e.g. submission reports, pre-registration numbers, pre-SIEF changes)
 - Download of invoices (coming from manual submission procedure)

What happens next?

- Next REACH-IT version (1.2.0) will be delivered to ECHA on the 8th of September
- Decision to go live will be taken after a successful outcome of:
 - Functional Site Acceptance testing
 - Performance testing
 - Security testing
- Main goal of this version is to phase out the temporary submission procedures
- Added functionality:
 - Registration dossier submission
 - Joint submission
 - Invoicing
 - Online dossier creation (Inquiry, ...)
 - Claiming of Registration number (nons)

What happens next? (2)

- Data submitted via the temporary submission procedures will be migrated into the system and made as transparent to the submitters as possible
- The TCC (technical completeness tests) module will not be fully operational before large scale testing has been performed
- All invoices will be manually verified before issued
- User manuals are being produced and other helpful tools/manuals are planned (Inquiry TCC tool, etc..)

Further releases of REACH-IT

concerning pre-registration / pre-SIEF

- dossier submission
 - registrants of phase-in substances will go in pre-SIEF
- upload of registration dossiers submitted using temporary procedures in the REACH-IT database
 - registrants of phase-in substances will go in pre-SIEF
- upload of information on substances regarded as registered (art. 15 - biocides and PPP)
 - implementation of specific module for ECHA to encode these substances, if phase-in, into pre-SIEF
- **More news will be published on ECHA website**

IUCLID 5 – Status vyvoja

- **pre-registracny modul (plug-in Tool) (uz dostupny)**
 - zjednodusi proces pre-registracie pre viacere latky
 - umoznuje pripravu
 - bulk-pre-registracny subor s viacerymi latkami, identifikovanymi pomocou EC cisla
 - single pre-registracny subor, ked latka nema EC-cislo
 - available as plug-in
mozno ho pripojit ako modul uz k instalovanej IUCLID 5 aplikacii bez velkej novej instalacie
 - viac ako 3800 krat bol downloaded



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SNIF migration plug-in (onedlho hotovy)

- umožňuje migráciu doterajšieho SNIF-suboru z momentálnej databanky pre nové latky do IUCLID 5 – formátu.
- testy v spolupráci JRC/ECHA s rôznymi typmi suborov dat (normal SNIF export files, fascikel s klasifikačnými a označovacími informáciami atd.)
 - momentálne sa skúša tento modul pre migráciu väčšieho množstva dat.
 - Treba ešte odstrániť niektoré „detské choroby“ systému



Dalsie projekty vo vyvoji

- **Service Release 1 (SR1) IUCLID 5**
 - odstranit chyby, ktore boli zistene
 - umoznit aj Window Vista aplikaciju
 - dodanie Update von IUCLID 5 instalacneho kitu pre ECHU je planovane este v septembri 2008
- **IUCLID 5 Query Tool plug-in**
 - system ma umoznit jednoduchsi pristup k specificky definovanim business-relevantnym informaciam
 - beta release dostala ECHA v auguste 2008
 - definitivne zavedenie asi v oktobri 2008

Planovane projekty

■ Web Services

ma zjednodusit operabilitu a znizit vydavky na software a na vymenu dat s roznyimi partnermi.

- Web Services maju umoznit komunikovat priamo s inymi partnermi / pocitacmi, nezavisle
 - od miesta, kde sa pocitac nachadza,
 - od operacneho systemu
 - od jazyka
- ma umoznit integrovanie IUCLID 5 s inymi ext. systemami v ramci REACH-IT
- **Termin:** ECHA dostane prvu verziu **koncom oktobra 2008.**

■ CSR plug-in

- prototyp je testovany momentalne v ECHA
- planovany termin dodavky do ECHA: **november 2008**

Planovane projekty

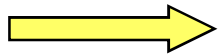
- **Preklady TGD (IT)**
- koncom decembra 2007 boli dokumenty (IUCLID 5 help/GD) poslane prekladatelskemu servisu
- prvý balik (technická časť manuálu pre spotrebiteľov) sa očakáva v októbri 2008
- kompletný balik – koncom novembra
- kompletná integrácia v rámci IUCLID 5 má byť hotová do konca 2008



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REACH Industry Portal

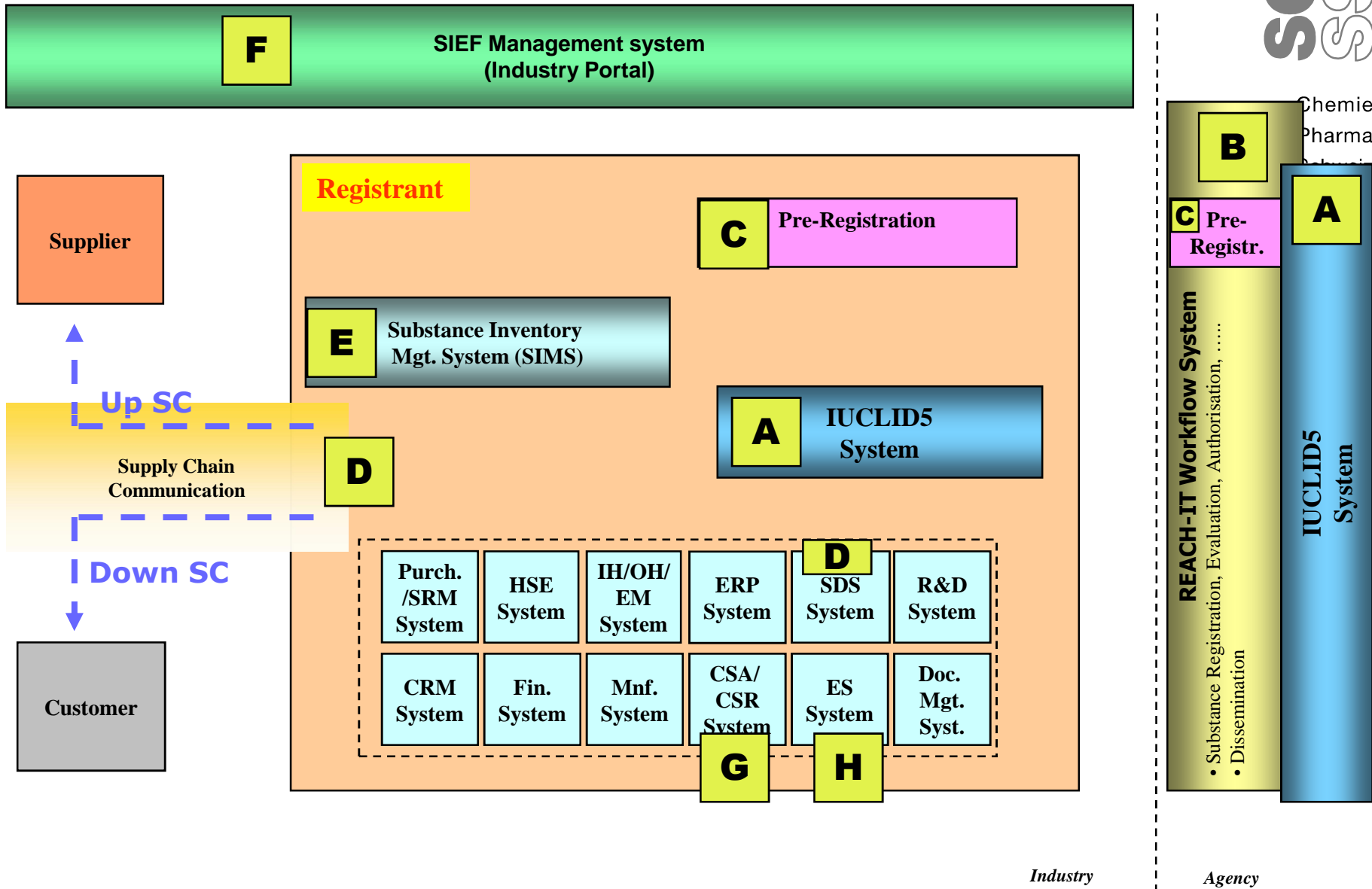
- **Focus on IT systems for REACH so far:**
 - **Company** level (IUCLID5, EHS, SDS, ERP,)
 - **ECHA** systems (REACH-IT, ...)
- **Need for industry IT layer, e.g. for:**
 - SIEFreach system
 - Common data libraries (Std. Phrases, RMM, Generic ES)
 - Shared documents
 -



Industry IT platform for REACH:

- Single point of access
- Consistent access to information, systems and tools
- Integrated security

IT systems for REACH -overview



Industry Portal - Status

■ Industry Portal:

• Driving forces:

- (Generic) Exposure Scenario (ES, GES) development
- Supply Chain Communication (SCC)
- Standard Libraries to support ES / SCC
- Integration / interfacing with related databases / portals e.g. ECHA, OECD

• SIEFreach is a good first step:

- Developed with Portal concept in mind
- Company / User Management built inside Portal

Industry Portal - Status

- **Current activities:**

- **Common Data being defined:**

- Various organisations working on data libraries, e.g. BDI, VCI, Bus. Europe, Sector Groups
 - ES and SCC project need additional data libraries

- **IT platform:**

- Portal software used to build SIEFreach
 - Proposal being developed for ES/SCC IT needs (Cefic / BASF) in a portal environment

- **Organisational:**

- Many organisations involved in ongoing activities

But, no concrete project and budget (yet) for next steps

SIEF – IT System: **ReachLink**

- CEFIC a narodne zväzy (VCI, CIA, UIC, Federchimica...) založili novu firmu - **ReachLink** s cieľom, uľahčiť komunikáciu v rámci SIEF.

System bol vyvinutý a je udržiavaný v prevádzke profesionálnou service-firmou – IBM

- System umožňuje:
 - jednoduchý kontakt medzi partnermi v rámci SIEF
 - kontrolu identity látok „sameness“
 - prístup k informáciám o datach, ktoré existujú a sú k dispozícii
 - výmenu informácií, prístup k chránenej oblasti diskusných skupín
 - vypracovanie spoločného registračného podania „joint submission“ a zostavenie konzorcii



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SIEF – IT System: **ReachLink (2)**

- **Financovanie:**

Vyvoj bol predplateny v ramci dohody zakladatelskych organizacii. Pouzivanie tejto platformy je financovany poplatkami za pouzivanie, ktore platia firmy, ktore sa do systemu prihlasia.

- **Poplatky:**

ca. 300 Euro pre latku a ucastnika pre celu dobu trvania REACH
Zlavy existuju pre SME (male a stredne podniky)

- System je od jula 2008 v prevadzke

- Informacie: www.reachlink-eu.com

- SIEFreach „live“ system stoji k dispozicii www.siefreach.com

Questions?

