

Le opinioni che “contano” a livello europeo: strumenti *on line*

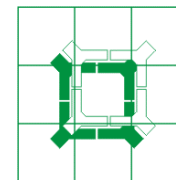
Silvia Boracchi

AGER

Regulatory Affairs & Product Safety, EFfCI

SICC, Milano, 13 dicembre 2005

AGGIORNAMENTO LEGISLATIVO

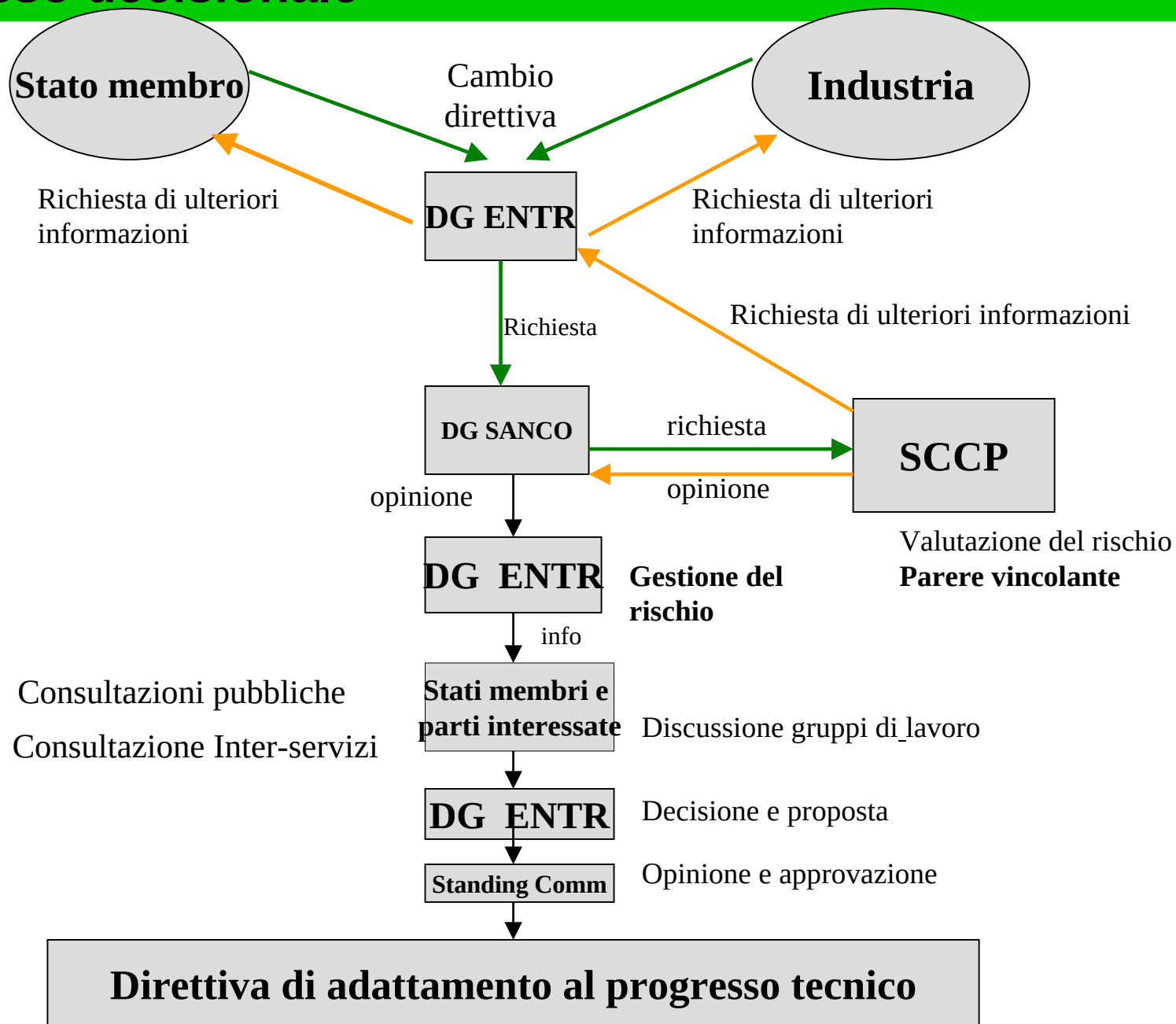


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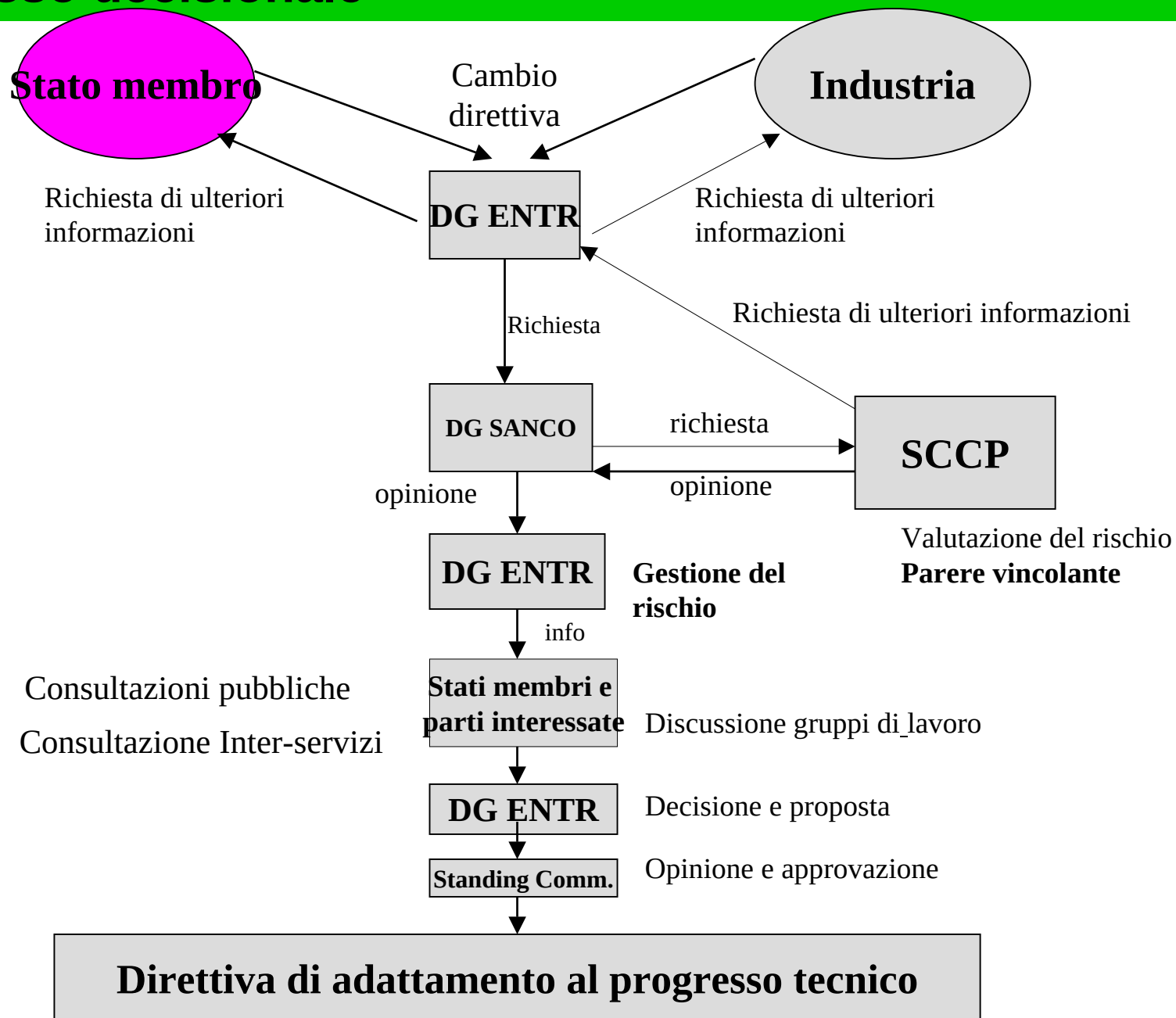
Sintesi

- Il processo decisionale legislativo in UE
- Gli attori principali e le fonti di informazione *on line*
- Alcuni esempi di strumenti per l'aggiornamento
- Considerazioni conclusive

Il processo decisionale



Il processo decisionale



Autorità nazionali degli Stati Membri

ITALIA:

Ministero della Salute
Direzione Generale della Valutazione dei Medicinali e della
Farmacovigilanza
Ufficio IX cosmetici

SPAGNA:

Subdirección de Productos Sanitarios
Agencia Española de Medicamentos y Productos Sanitarios
Ministerio de Sanidad y Consumo

.....

http://pharmacos.eudra.org/F3/cosmetic/cosm_member_states_contacts.htm

Cosmetics

Directorate-General Enterprise and Industry, Unit F3 - Cosmetics and Medical Devices

European Commission



Industry facts & figures Legal and regulatory aspects Scientific and technical Committees & working groups National authorities Other information Public consultations Contacts What's new

EU Member States contacts



Malta

Belgium
Czech Republic
Denmark
Germany
Estonia
Greece
Spain
France
Ireland
Italy

Cyprus
Latvia
Lithuania
Luxembourg
Malta
Hungary
Netherlands
Austria
Poland
Portugal

Slovenia
Slovakia
Finland
Sweden
United Kingdom

EFTA / EEA States contacts

Norway
Iceland
Liechtenstein
Switzerland

Communication tools for members (DG Enterprise and Industry)



Autorità nazionali degli Stati Membri

FRANCIA:

Agence française de sécurité sanitaire des produits de santé (AFSSAPS)

“Ensuring health safety standards remain optimum, while at the same time promoting innovation when it is genuine and when it meets the important needs of patients”

<http://afssaps.sante.fr/>

Agence française
de sécurité sanitaire
des produits de santé



veautés | Sécurité sanitaire & vigilances | Documentation & publications | Rôle & missions | Infos pratiques | Experts & emplois

propos du

an du site

archives

contacts

ste de diff

information

recherche

jet d'établ

ency work

yecto de c

jekt 2005-2007

afssaps évalue la sécurité
emploi des produits de santé
médicaments, produits biologiques,
dispositifs médicaux, cosmétiques...)
ne assure leur surveillance,
contrôle leur qualité en laboratoire
inspecte les sites de fabrication,
distribution et d'essais.
ne mène des actions d'information
sur le bon usage des
produits de santé.

e

expertise au service de la décision". Audition publique -
tribution du Directeur Général - (06/12/05)

ports publics d'évaluation :

nta 24 mg & Mélagatran 3 mg / 0,3 ml pdf 56 ko (02/12/05)

cution d'ouverture du Directeur Général - "Les défis de
ouvelle législation communautaire"- IFIS (21-22 nov05)

t de la commercialisation de la spécialité TRANXENE

ng, comprimé pelliculé sécable (22/11/05)

cins contre la grippe saisonnière : recommandations

prescription et de délivrance (17/11/05)

ommandations de bonne pratique : mise à jour de la

rubrique. Antibiothérapie par voie générale en pratique
courante dans les infections respiratoires (08/11/05)

■ REMINYL® : informations sur la sécurité d'emploi liées
aux résultats finaux d'études cliniques menées dans les
troubles cognitifs légers (MCI) (08/11/05)

■ Article du Directeur Général - "Sécurité sanitaire : les défis
de l'Afssaps"- Revue Sève (octobre/novembre2005)

communiqués de presse

■ Rappel des différentes étapes et expertises menées
préalablement à la greffe partielle de la face, réalisée le 27
novembre 2005. (07/12/05)

liens directs

➤ **DM / DMDM**

➤ Biotox/Piratox

➤ Grand froid et médicaments

➤ Alertes de sécurité sanitaire

• Dernières alertes

• Retraits de lots

• Retraits de produits

• Infos/recos

➤ Ruptures de stocks

➤ Lettres aux prescripteurs

➤ Les mises au point

➤ RAPPE

➤ RBP

➤ ATU

➤ Préparations hospitalières

➤ Répertoire des spécialités
pharmaceutiques

➤ Essais cliniques

➤ Répertoire des génériques

➤ Répertoire des établissements
pharmaceutiques



légende des icônes des produits de santé

- MED** médicament
- DIV** dispositif de diagnostic in vitro
- DM** dispositif médical
- THA** tissu ou organe d'origine humaine ou animale
- COS** produit cosmétique
- PTA** produit thérapeutique annexes
- PSL** produit sanguin labile
- AUT** autres produits de Santé
- MDS** médicament dérivé du sang
- PTG** produit de thérapie génique
- PCT** produit cellulaire à finalité thérapeutique

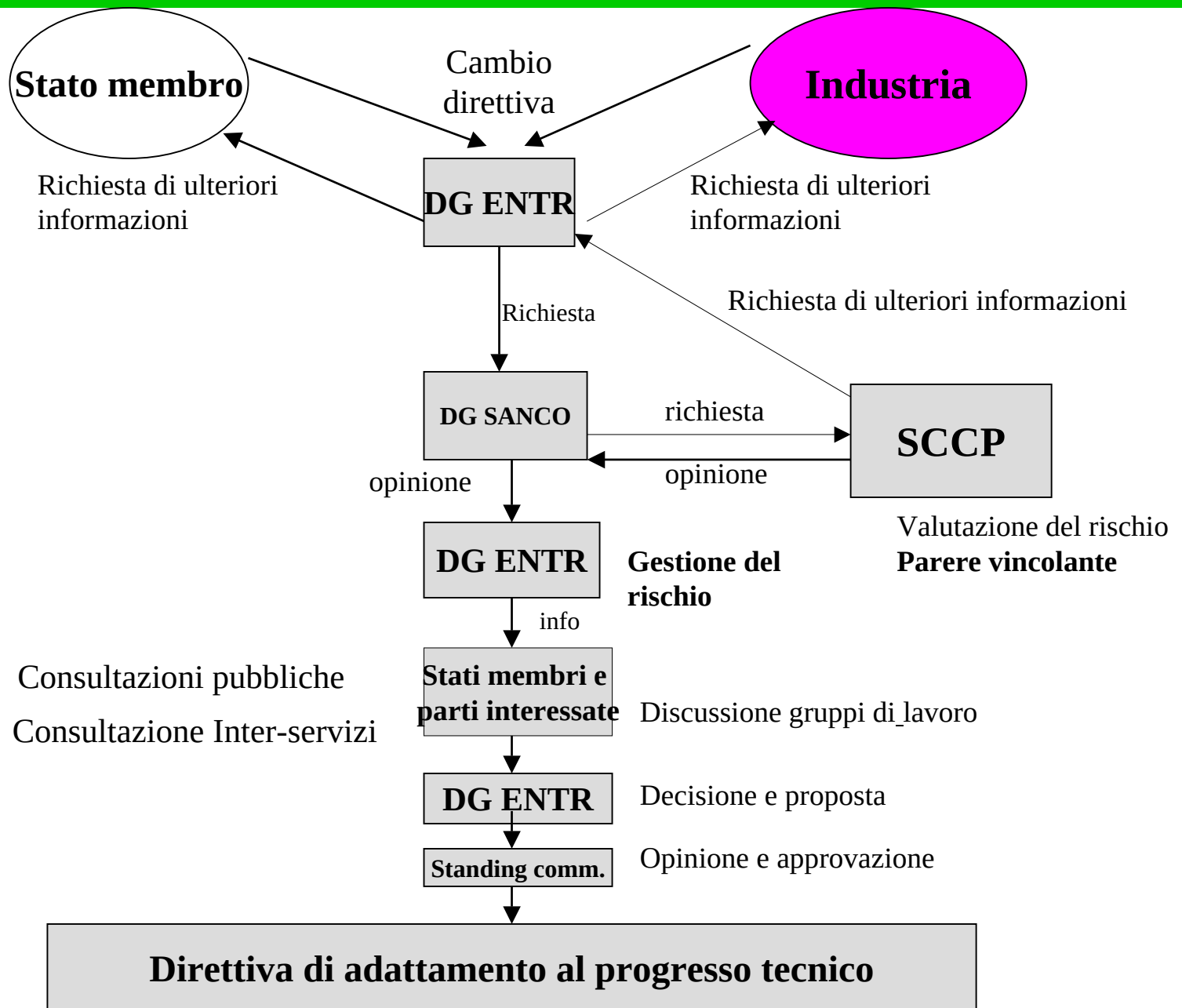
Cette rubrique regroupe les décisions de police sanitaire prises par l'Afssaps depuis le premier janvier 2004, à l'exception des retraits d'AMM qui seront inclus dans cette rubrique courant 2005.

année 2005

cliquez sur l'intitulé de la décision- les décisions sont en format pdf

date de mise en ligne	type de produit	intitulé de la décision	date de la décision
23/11/05	COS	Décision soumettant à des conditions particulières et à des restrictions la fabrication, le conditionnement, l'importation, la distribution en gros, la mise sur le marché à titre gratuit ou onéreux, la détention en vue de la vente ou de la distribution à titre gratuit ou onéreux et l'utilisation de produits cosmétiques contenant certains éthers de glycol (<i>version corrigée du 25/11/2005</i>)	23/11/05
21/11/05	COS	⚠ Voir la décision du 23/11/05 qui annule et remplace la décision du 18/11/05	18/11/05
14/09/05	MED	Suspension pour une durée d'un an de l'activité de fabrication de médicaments à usage humain de la société "V2 MED"	06/09/05
14/09/05	MED	Suspension jusqu'à mise en conformité et pour une durée maximum d'un an de l'activité de fabrication de	31/08/05

Il processo decisionale



Produttori di Cosmetici finiti

COLIPA, The European Cosmetic, Toiletry and Perfumery associat.
www.colipa.com

e le singole associazioni nazionali:

UNIPRO www.unipro.org

CTPA www.ctpa.org.uk

IKW www.ikw.de

.....



CTPA WHITE PAPERS

About the CTPA

Cosmetic markets

Cosmetic regulations

Information centre

- About cosmetics
- Frequently Asked Questions
- Published articles
- CTPA published research
- CTPA white papers**
- Look Good... Feel Better
- Educational resources

Members intranet

Useful links

Printable version

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Password

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Quick Search for

[Advanced Help](#)

Risk in Perspective

The CTPA is pleased to launch its second White Paper "Risk in Perspective". We all face the challenge of putting risk into perspective in our everyday lives and in this new paper we set out to understand more about how we do this.

Our industry faces the challenge to put risk into perspective and demonstrate the difference between risk and hazard. In this paper we argue that consumers deserve more credit for holding sensible attitudes to risk. It challenges perceptions, often created by NGOs and the media, of a society frightened of the results of scientific developments and scared of everyday products. What is clear from this research is that when given information in a balanced way, consumers understand the benefits of scientific progress and also appreciate that zero risk in life is impossible.

This paper builds on our previous calls to action, including closer collaboration between NGOs, government, industry and the media, to create a climate in which people are able to make sense of the right information. We want recognition of the need to provide clear and accessible information that relies on people's ability to put risk into perspective. In short, to trust in their own good sense.

We welcome comments on the content and conclusions of this CTPA White Paper (info@ctpa.org.uk). If you wish to share it with others please make use of the link below. Hard copies are available on request.

[White Paper 'Risk in Perspective'](#)

Making Sense of Risk

This is a discussion paper published in response to a growing recognition amongst industry, politicians, NGOs, media and consumers that the debate around what has been called the "worry society" is one in which we all need to engage.

Our industry faces the challenge to put risk into perspective and demonstrate the difference between

Produttori di Ingredienti: EFfCI

EFfCI, The European Federation for Cosmetic Ingredients

www.effci.com

- ✓ **MANDATO:** rappresentare gli interessi dell'Industria in ambito politico, amministrazione UE, clienti e nei forum scientifici
- ✓ **MEMBRI:**
 - **ASSOCIAZIONI nazionali**
 - **MEMBER COMPANIES** (AUSTRIA, BELGIUM, FRANCE, SWITZERLAND, THE NETHERLANDS)

Produttori di Ingredienti: EFfCI

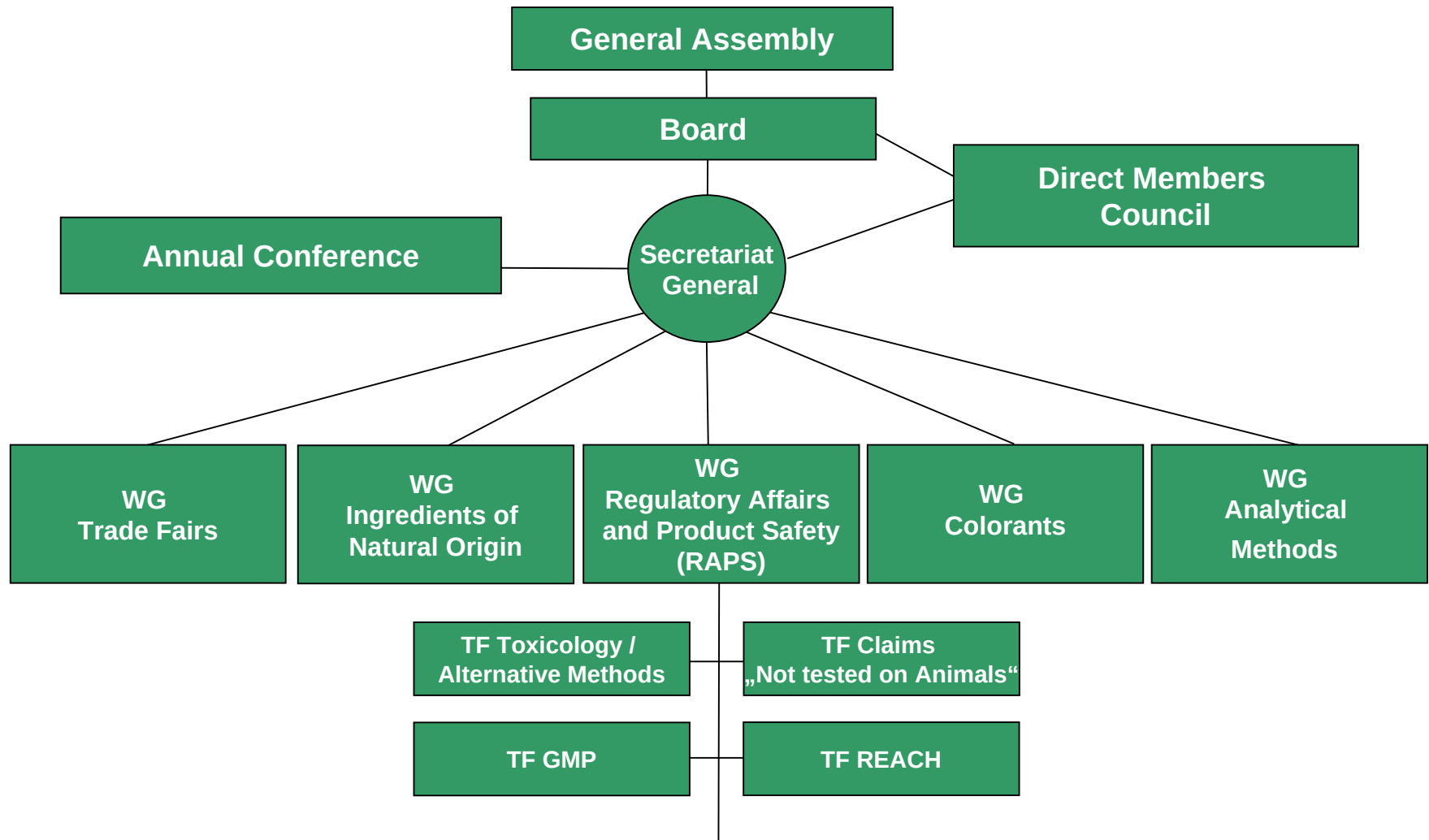
ASSOCIAZIONI nazionali affiliate ad EFfCI:

MAPIC, Italia: <http://acfis.federchimica.it>

KOSRO/TEGEWA, Germania: www.tegewa.de

COSRAM/BACS, UK: www.bacsnet.org

Gli attori e le fonti



EFfCI Organisation

Produttori di Ingredienti: EFfCI

www.effci.com

- ✓ **parte PUBBLICA** (testo consolidato della Dir Cosmetici, inventario INCI)
- ✓ **sezione RISERVATA AI SOCI: *EFfCI database***
 - EFfCI *NEWS*
 - position papers di EFfCI (claims, 26 allergens, GMP, etc)
 - verbali dei WG EFfCI
 - studi e rapporti (ECVAM report, studio di letteratura sui 26 allergeni, etc)

Private part

About EFfCI

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Cosmetic Regulation

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EFfCI EVENTS



EFfCI NEWS

Newsletter



EFfCI Position Paper



Publication



WORKING GROUPS

Minutes, Working documents



The European Federation for Cosmetic Ingredients

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EFFCI Activities

Please select Documents from this Folder. You can open and close the Menu with  and . (Windows-like)



EFFCI Position Paper

- 2005.06 - EFFCI PP - Timetable Tox endpoint.pdf
- 2005.05 - EFFCI PP - Legal Action VII Amendment.pd
- 2005.05 - EFFCI PP - EFFCI GMP for cosmetic ingred
- 2005.05 - EFFCI PP - Claim referring on animal tes



EFFCI PP - Allergens

- 2005.05 - EFFCI PP - Allergens.pdf
- 2004 - Allerges - Literature research.pdf
- Allergens - Category 2 - updated from WG INO.pdf



Monographies

Produttori di Ingredienti: EFFA

www.effa.be

✓ sezione RISERVATA AI SOCI

✓ parte PUBBLICA:

Legislation

➤ **SAFETY** of food products (additives/flavourings, hygiene); GMOs (DG SANCO, Food & Feed Safety)

➤ **SCIENTIFIC ADVICE:**

EFSA

Scientific Comm. on Food



Welcome Events **Legislation** Our Members Contact Us Links Member Network



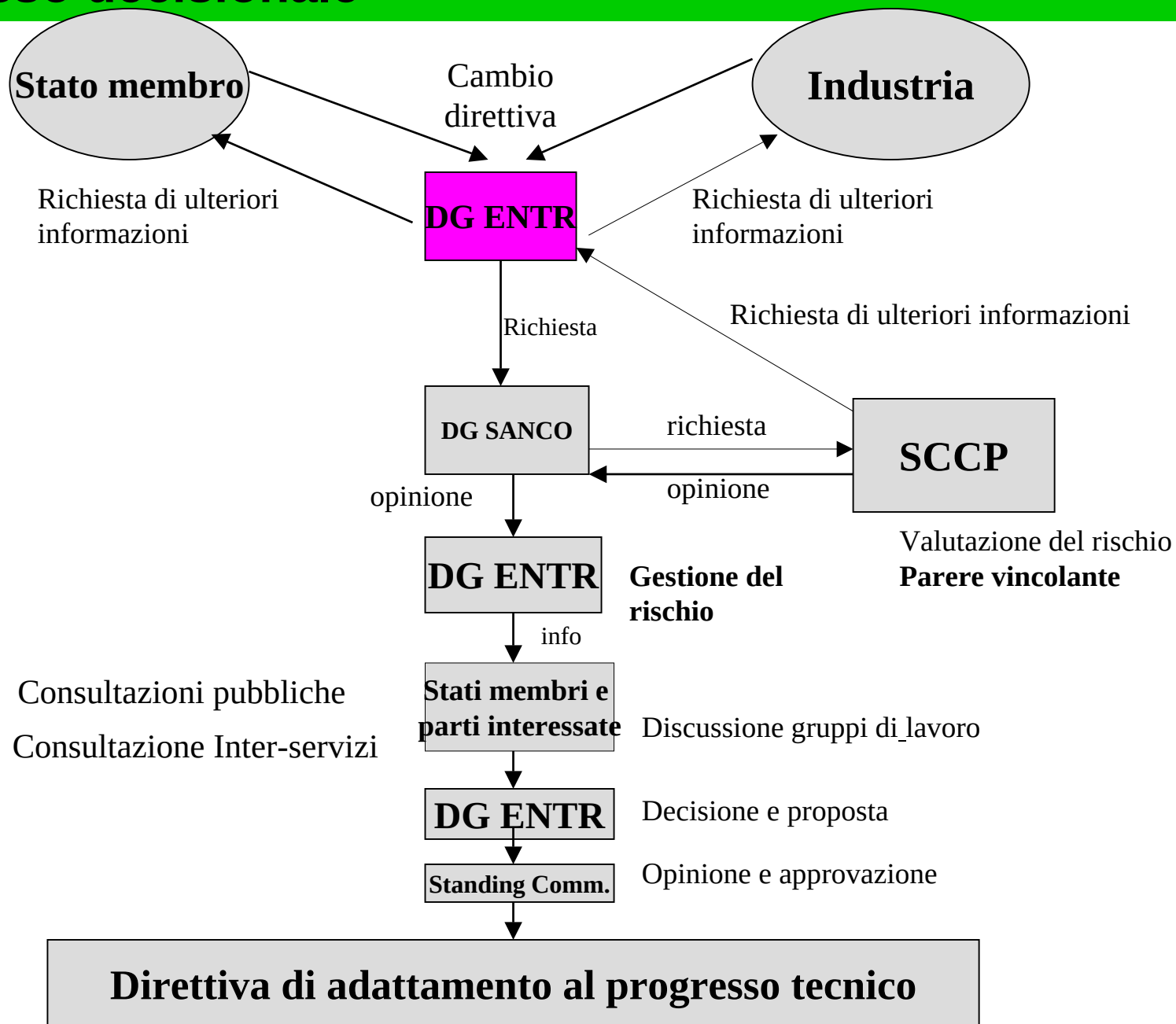
Flavours play an important role in many final consumer products, not quantitatively, but certainly qualitatively. The European legislators pay more and more attention to flavours used in consumer products and are showing a strong interest in their health and environmental aspects.

EFFA monitors European developments in the key areas for the industry such as:

Single Market:

1. Safety of Food Products:
 - [Food additives](#)
 - [Flavourings](#)
 - [Food Hygiene](#)
2. [Food Labelling](#)
3. [Genetically Modified Organisms \(GMOs\)](#)
4. Scientific Advice:
 - [European Food Safety Authority](#)
 - [Scientific Committee](#)
 - [Regulatory Committee](#)
 - Evaluation Programme:
 - [FGE.01](#)
 - [FGE.02](#)

Il processo decisionale



EU COM

25 COMMISSARI (e più di 24.000 funzionari!)

36 DIPARTIMENTI (Direzioni **G**enerali)

www.europa.eu.int

DG ENTERPRISE and INDUSTRY

www.europa.eu.int/comm/enterprise/chemicals

DG ENTR, Unit F3

Directorate-General ENTERPRISE and INDUSTRY, Unit F3
Cosmetics and Medical Devices

- **competitiveness issues** of the European industry
but also
- **administering the Cosmetics Directive** and
supervising its correct implementation

www.pharmacos.eudra.org

European Commission



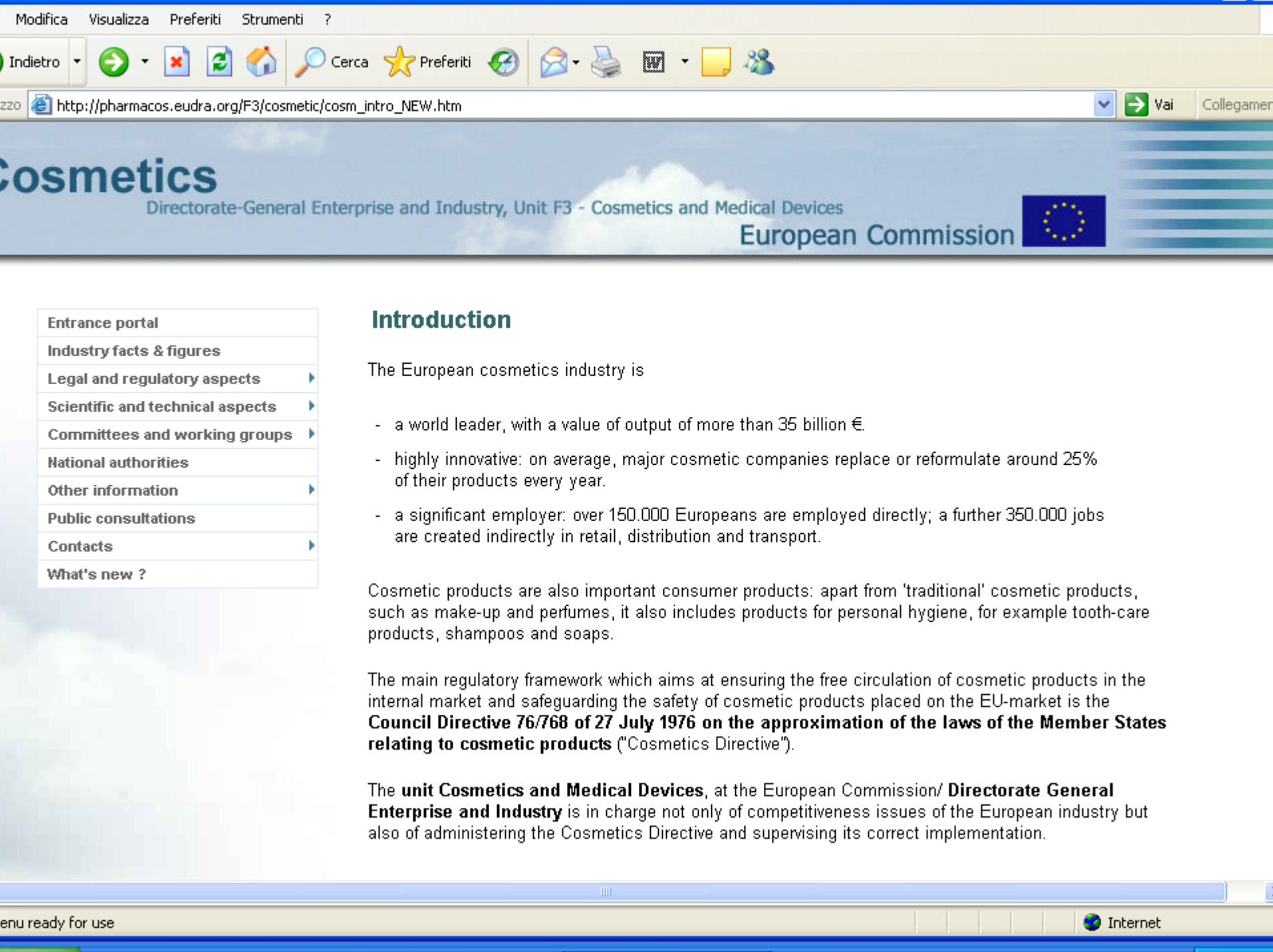
Enterprise and Industry DG
Directorate F - Consumer goods

F2
Pharmaceuticals

F3
Cosmetics >>>

Medical Devices >>>

G10
High Level Group on innovation
and the Provision of Medicines



Entrance portal
Industry facts & figures
Legal and regulatory aspects
Scientific and technical aspects
Committees and working groups
National authorities
Other information
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Contacts
What's new ?

Introduction

The European cosmetics industry is

- a world leader, with a value of output of more than 35 billion €.
- highly innovative: on average, major cosmetic companies replace or reformulate around 25% of their products every year.
- a significant employer: over 150.000 Europeans are employed directly; a further 350.000 jobs are created indirectly in retail, distribution and transport.

Cosmetic products are also important consumer products: apart from 'traditional' cosmetic products, such as make-up and perfumes, it also includes products for personal hygiene, for example tooth-care products, shampoos and soaps.

The main regulatory framework which aims at ensuring the free circulation of cosmetic products in the internal market and safeguarding the safety of cosmetic products placed on the EU-market is the **Council Directive 76/768 of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products** ("Cosmetics Directive").

The **unit Cosmetics and Medical Devices**, at the European Commission/ **Directorate General Enterprise and Industry** is in charge not only of competitiveness issues of the European industry but also of administering the Cosmetics Directive and supervising its correct implementation.

DG ENTR, Unit F3

www.pharmacos.eudra.org

➤ **“Comparative Study on Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products”**

RPA, agosto 2004

- ☐ **aspetti TECNICO-REGOLAMENTARI**
- ☐ **aspetti SCIENTIFICI e TECNICI**
- ☐ **COMITATI e WG**
- ☐ **CONSULTAZIONI PUBBLICHE**
- ☐ ***What's new?***

DG ENTR, Unit F3

TECNICO-REGOLAMENTARE

CoE

OECD

ECVAM

SIS

www.pharmacos.eudra.org

What's new?

TECNICO-SCIENTIFICA

COMITATI e WG

SCCP

CONSULTAZIONI pubbliche

DG ENTR, Unit F3

www.pharmacos.eudra.org

❑ aspetti **TECNICO-REGOLAMENTARI**

- ✓ **Guidelines:** “Period-after opening-labelling”
“Borderline Products”: *Guidance Documents*
(Biocidal, Medicinal products)
- ✓ **Animal testing:**

1. Timetables for phasing out
2. ECVAM report
3. Conference on Alternatives - Brussels, 7th November 2005
4. 3 Rs Declaration

DG ENTR, Unit F3

www.pharmacos.eudra.org

❑ **aspetti TECNICO-REGOLAMENTARI**

✓ **Animal testing**

- Council of Europe: www.coe.int
- OECD: www.oecd.org
- ECVAM: <http://ecvam.jrc.it/>

✓ **Altro:** inventario INCI
altre leggi applicabili (aerosols, packaging, contenuto)

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http://book.coe.int/EN/recherche_avancee.phpVaiCollegamento

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Keyword Search :

Books

Plants in cosmetics: plants and plant preparations used as ingredients for cosmetic products - volume 2 (2001)
92-871-4676-4
Prof. Robert Anton, Dr. Franco Patri, Prof. Vittorio Silano

This study contains 44 datasheets on plants and plant preparations which have been evaluated by the Council of Europe's Committee of Experts on Cosmetic Products. An assessment of the safety of these plants and plant preparations is also included.

Plants in cosmetics: Plants and plant preparations used as ingredients for cosmetic products - Volume 1 (2002)

Pages of the site

Mailing list
(Monday 1st December 2003)
... addiction blood transfusion medical professions medication & pharmacopoeia doping medical search aids handicaps social security health policy flavourings cosmetics genome transplantation cloning social issues employment minorities migrants & refugees elderly racism & ...

Advanced search
(Saturday 1st November 2003)
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A tour of the Europe Prize towns (2005)

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Internet

ECVAM,

European Center for the Validation of Alternative Methods

<http://ecvam.jrc.it/>

- ✓ **Descrizione struttura e attività**
- ✓ **Elenco metodi validati e pubblicazioni**
- ✓ **Procedure per la sottomissione di test methods**
- ✓ **Eventi e meetings**
- ✓ **Links: JRC; DG ENT, RES, SANCO, ENV...**

→ Scientific Information Service (SIS):

<http://ecvam-sis.jrc.it/>



European Centre for the Validation of Alternative Methods

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About ECVAM

Activities

Validated Methods

Publications

Submission of new
Test Methods to ECVAM

News Events and
Meetings

Downloads



Regularly updated about ECVAM? Subscribe to the mailing list!



The SIS databases provide factual information on alternative methods to animal experiments at any stage of development



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
Joint Research Centre

SIS

Scientific Information Service on advanced alternative methods

<http://ecvam-sis.jrc.it/>

- ✓ **Descrizione Metodi e Studi di Validazione**
- ✓ **Bibliografia**
- ✓ **Laboratori tox e farmacologia (in preparazione)**
- ✓ **ECVAM reports (workshops, task forces)**

DG ENTR, Unit F3

www.pharmacos.eudra.org

- ✓ **aspetti TECNICO-REGOLAMENTARI**
- ❑ **aspetti SCIENTIFICI e TECNICI**
- ❑ **COMITATI e WG**
- ❑ **CONSULTAZIONI PUBBLICHE**
- ❑ ***What's new?***

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aspetti SCIENTIFICI e TECNICI

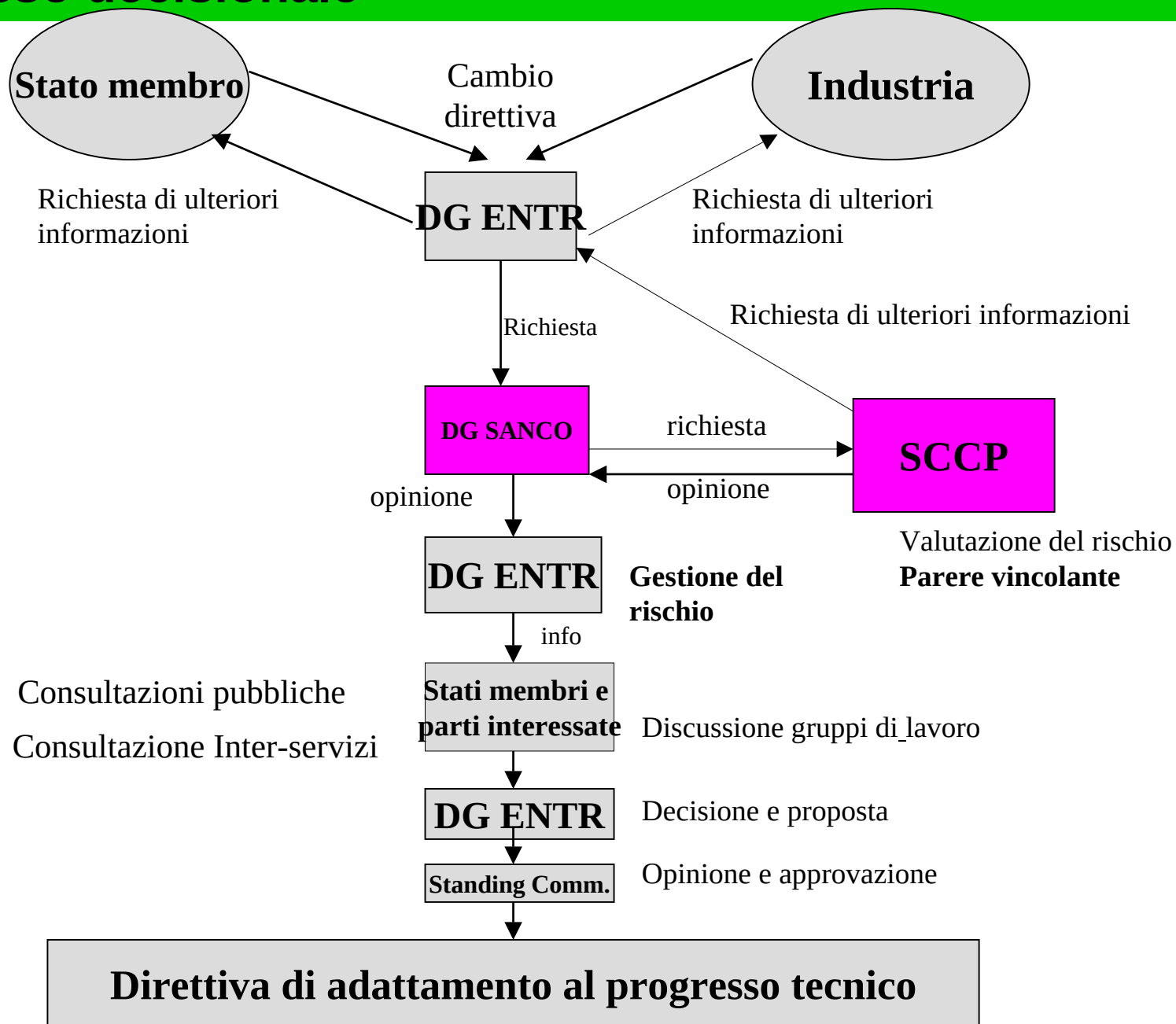
- ✓ **Testing guidance** (*SCCNFP's Notes of Guidance for the testing of cosmetic ingredient and their Safety Evaluation, 5th rev., October 2005*)
- ✓ **Metodi di analisi** (*verifica della composizione*)

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- ✓ **aspetti TECNICO-REGOLAMENTARI**
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- ❑ ***What's new?***

Il processo decisionale



DG ENTR, Unit F3

www.pharmacos.eudra.org

COMITATI e Working Groups

SCCP, (SCCNFP):

mandato

composizione

agenda

opinioni

http://europa.eu.int/comm/health/ph_risk/committees/04_sccp/04_sccp_en.htm

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OECD

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SIS

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What's new?

TECNICO-SCIENTIFICA

COMITATI e WG

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What's new?

- ✓ **RAPEX:** notifiche in corso
- ✓ **DOCUMENTI ATTUALI**
 - press release
 - consultazioni COM
 -

DG ENTR, Unit F3

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PUBLIC CONSULTATIONS

Sono richiesti commenti su

- impatto per la **competitività** e il **mercato**
- **costi** diretti e indiretti per l'industria
- impatto sull'**innovazione** e la **ricerca**
- impatto per settori e gruppi specifici di **lavoratori**
- conseguenze per i **consumatori**

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❑ PUBLIC CONSULTATIONS

- ✓ **MDBGN** —————> bando?
- ✓ **Lawson** —————> bando?
- ✓ **4-MBC** —————> dati per il 31.12.05

per la consultazione su MDBGN: entr-cosm-MDBGN@cec.eu.int

per la consultazione su 4-MBC: entr-cosm-4MBC@cec.eu.int

per la consultazione su lawson: entr-cosm-lawson@cec.eu.int

entro
16.12.05

DG ENTR, Unit F3

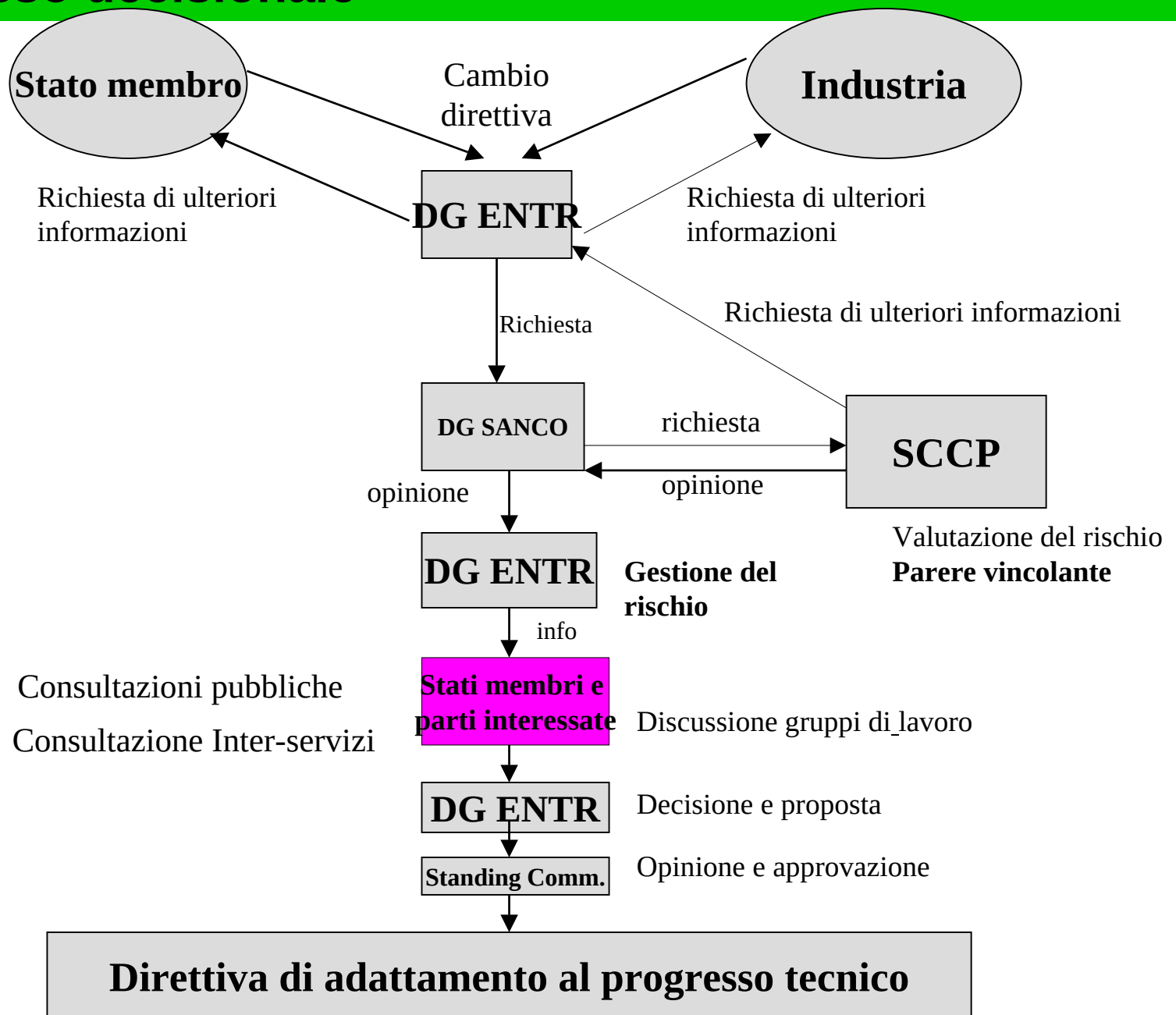
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PUBLIC CONSULTATIONS

PRESERVANTI con asterisco:

- dati entro il 31.12.05
- consultazione entro il 31.10.05

Il processo decisionale



EU WG on COSMETICS (AHWP)

- ❑ Stati Membri
- ❑ Industria
- ❑ COM – DG ENTR F3

- ❑ BEUC: www.beuc.org *organizzazione europea consumatori*
- ❑ EFTA: www.efta.int *European Free Trade Association*
- ❑ ECEAE: www.eceae.org
European Coalition to End Animal Experiments
- ❑ ECOPA: <http://ecopa.vub.ac.be>
European Consensus-Platform for Alternatives

draft AGENDA - 8 dicembre 2005

- ***Skin allergens*** (cosmetovigilance, self-testing)
- ***7th November 2005***: follow up
- Guidelines on ***restriction to professional use*** (sub-group)
- Manual on ***demarcation line with the Medicinal products Directive 2001/83/EC and the Medical devices Directive 93/42/EEC*** (sub-group)
- ***Perfumes***: follow-up of SCCNFP/SCCP opinions
- Follow-up of ***SCCP opinions*** (AHA, IPBC, ...)
- Hair dyes, ***public consultations***