



DECERNIS

- Conformité réglementaire des matériaux au contact alimentaire
- Edition des certificats d'alimentarité

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Quels enjeux?

Secur'Food
Paris, November 29, 2011

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Déclaration de Conformité des emballages: Exigences réglementaires UE

- **Exigences générales: Règlement (EC) No 1935/2004**
 - **Article 16(1):** Obligation d'accompagner les emballages d'une déclaration écrite attestant leur conformité avec les règles qui leur sont applicables.
 - **Annexe I:** Idem pour les éléments non plastique (colles, encres, vernis et revêtements, etc.)
- **Exigences Plastiques: Règlement (UE) No 10/2011, Chapitre IV**
 - **Article 15:** Applicable tout au long de la chaîne de production, depuis les matières premières et les stades intermédiaires de fabrication jusqu'au Produit Fini.
 - La Déclaration doit être renouvelée lorsque des modifications substantielles de la composition ou de la production induisent des changements de la migration.
 - **Article 16:** une documentation appropriée justifiant la Déclaration de Conformité doit être disponible sur demande des autorités nationales compétentes.
 - **Annexe IV:** liste des informations requises pour la Déclaration de Conformité



Critères d'acceptation des matériaux

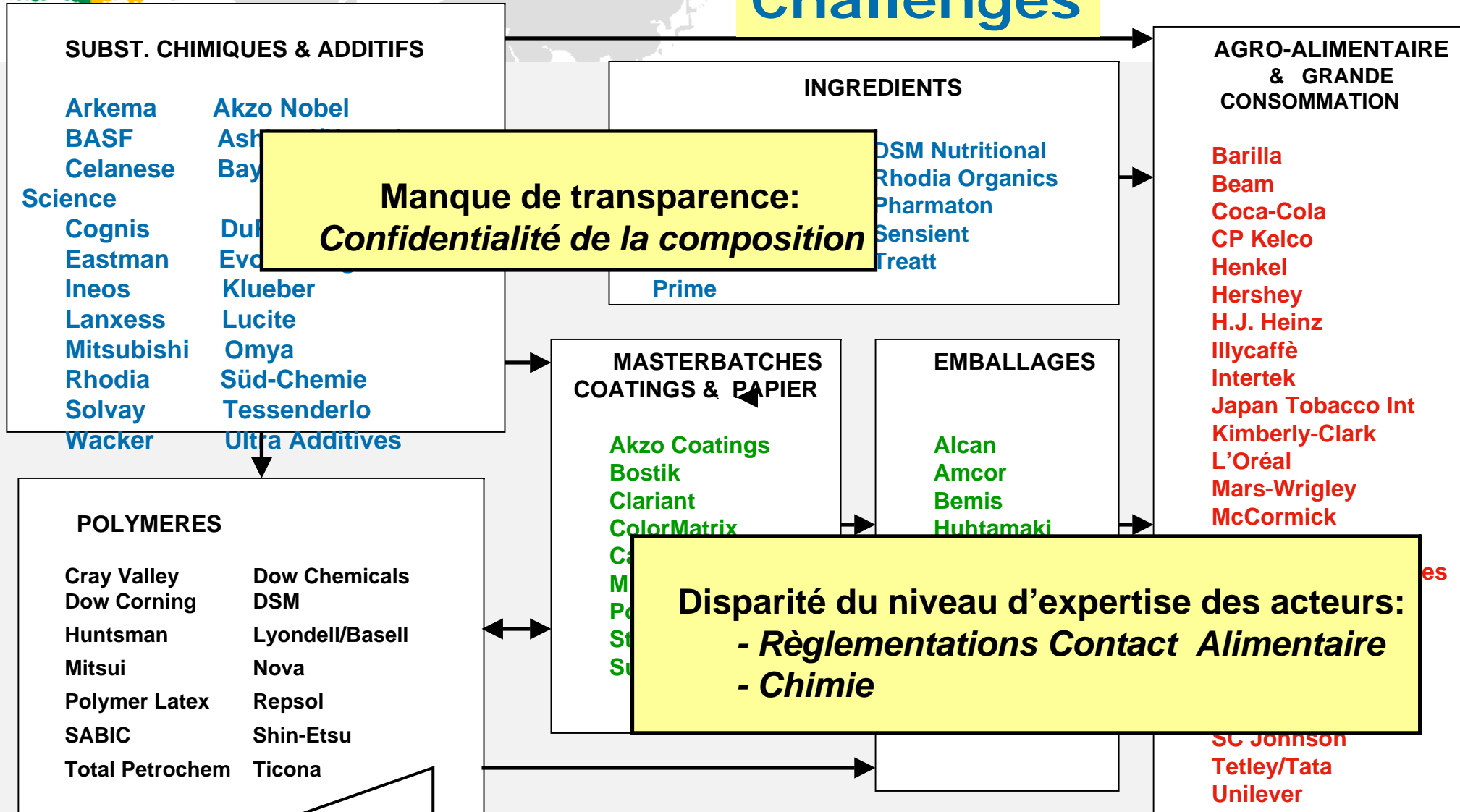
- **Selon:**

- Contraintes réglementaires du pays de destination.
- Normes d'approvisionnement ou questionnaires spécifiques du client.
- Bonnes pratiques du secteur industriel ou d'Associations professionnelles.

Répondre aux questionnaires des services Achat prendra plus de temps qu'une simple Déclaration de Conformité, vu que ces questionnaires contiennent de nombreuses questions relatives à différents sujets réglementaires.

Flux d'information sur la Supply Chain:

Challenges

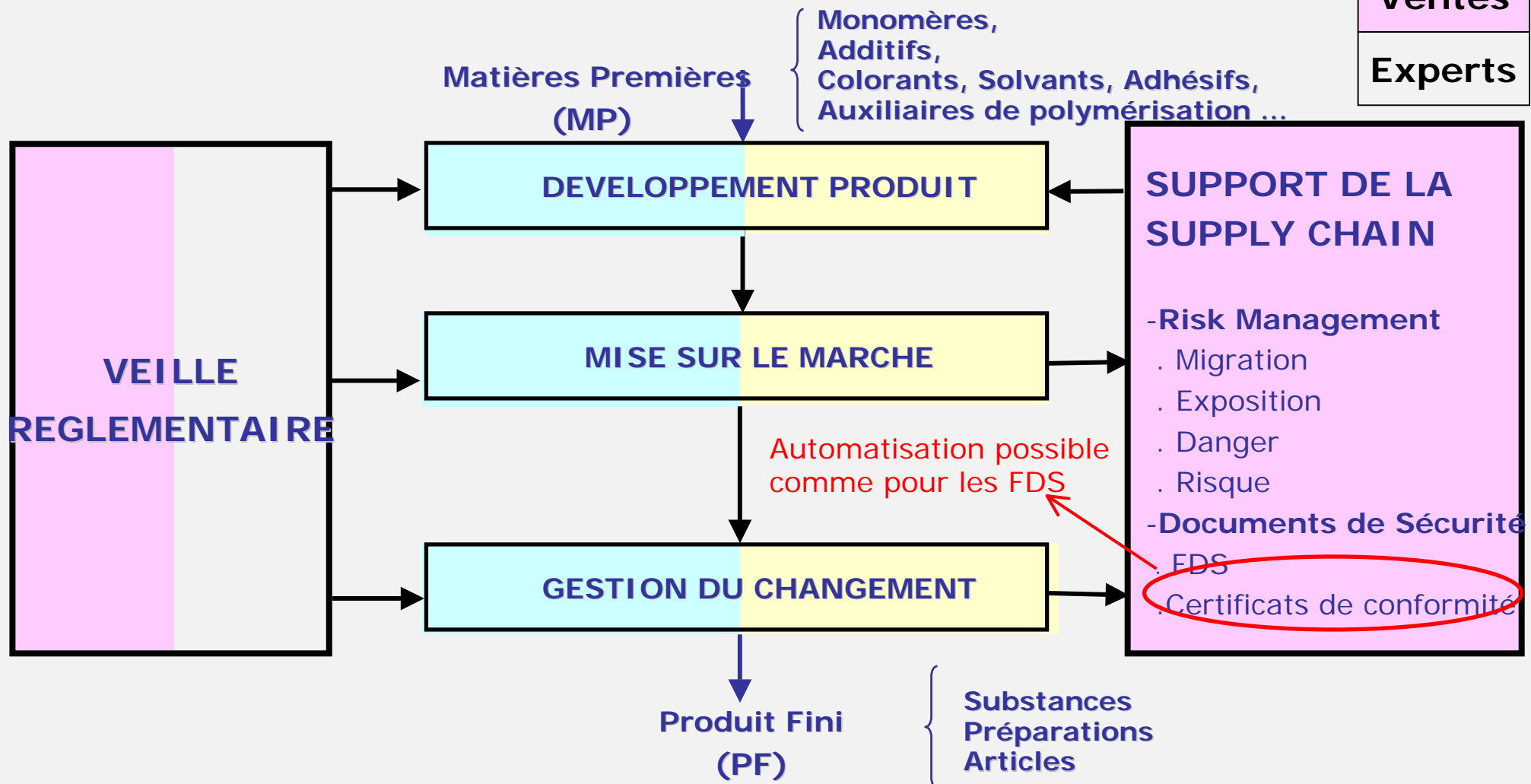


AGENCES REGLEMENTAIRES US FDA, DG SANCO, EFSA, EU JRC, OECD, NINFS, JHOSPA, NIHS

Business Process & Cycle de vie du Produit

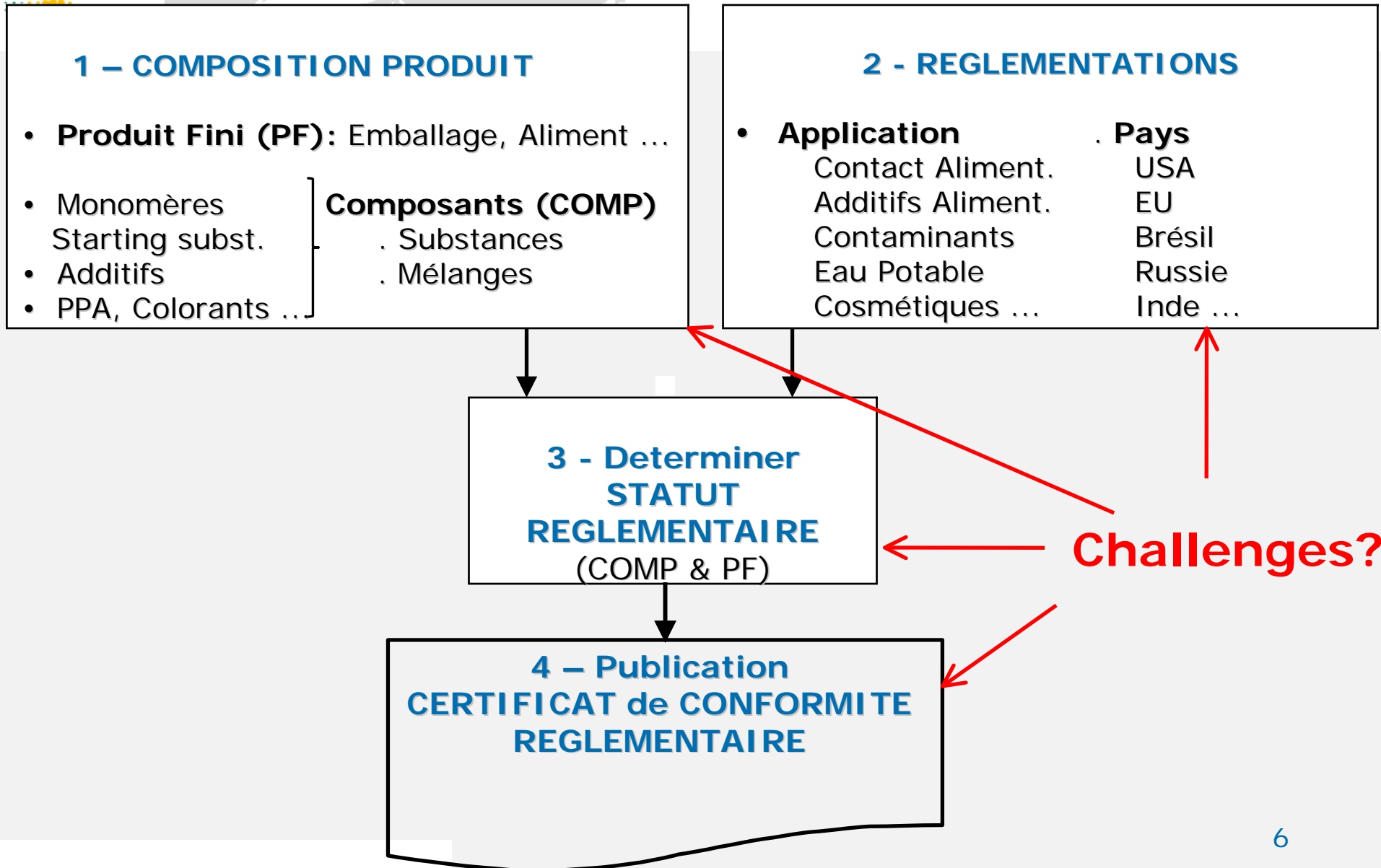
Nombreux Acteurs:

R & D
Production
Ventes
Experts



Les contraintes réglementaires impactent la totalité du cycle de vie du Produit

Conformité Règlementaire: un processus universel





Challenge: Composition Produit

- **Connaissance de la composition détaillée dépend de la position sur la Supply chain (CBI)**

Additifs > Polymères > Emballage > Agro-alimentaire

- **Composants disponibles (ou non!) dans l'ERP:**

- Substances pures avec un N°CAS

ou

- Matières Premières (mélange de substances):

- identifiées avec la clé produit de l'ERP

- composition complète pas forcément connue

- Fonction des composants (monomère, additif, colorant ...)

- pas forcément disponible dans la base composition

- **Entrée de la composition à partir:**

- d'une interface avec l'ERP

- d'un tableau Excel



Challenge: Suivi des Règlementations

- **Plus de 3 000 réglementations Matériaux au contact alimentaire pour 70 pays:**

Besoin de personnel dédié à la veille réglementaire.

- **Référence à une famille**

Ungesättigte aliphatische Mono- und Dicarbonsäuren C3-C8
dans BFR plutôt qu'à une substance spécifique (e.g. Acide crotonique)

- **Substances citées avec noms peu communs:**

'Phenol, 4,4'-(1-methylethylidene)bis' pour Bisphenol A

- **Incorporation par référence:**

21 CFR 176.170 / 180 (Food contact Paper & board) incorpore des centaines d'autres réglementations CFR.

- **Extraire les 'données réglementaires' des réglementations:**

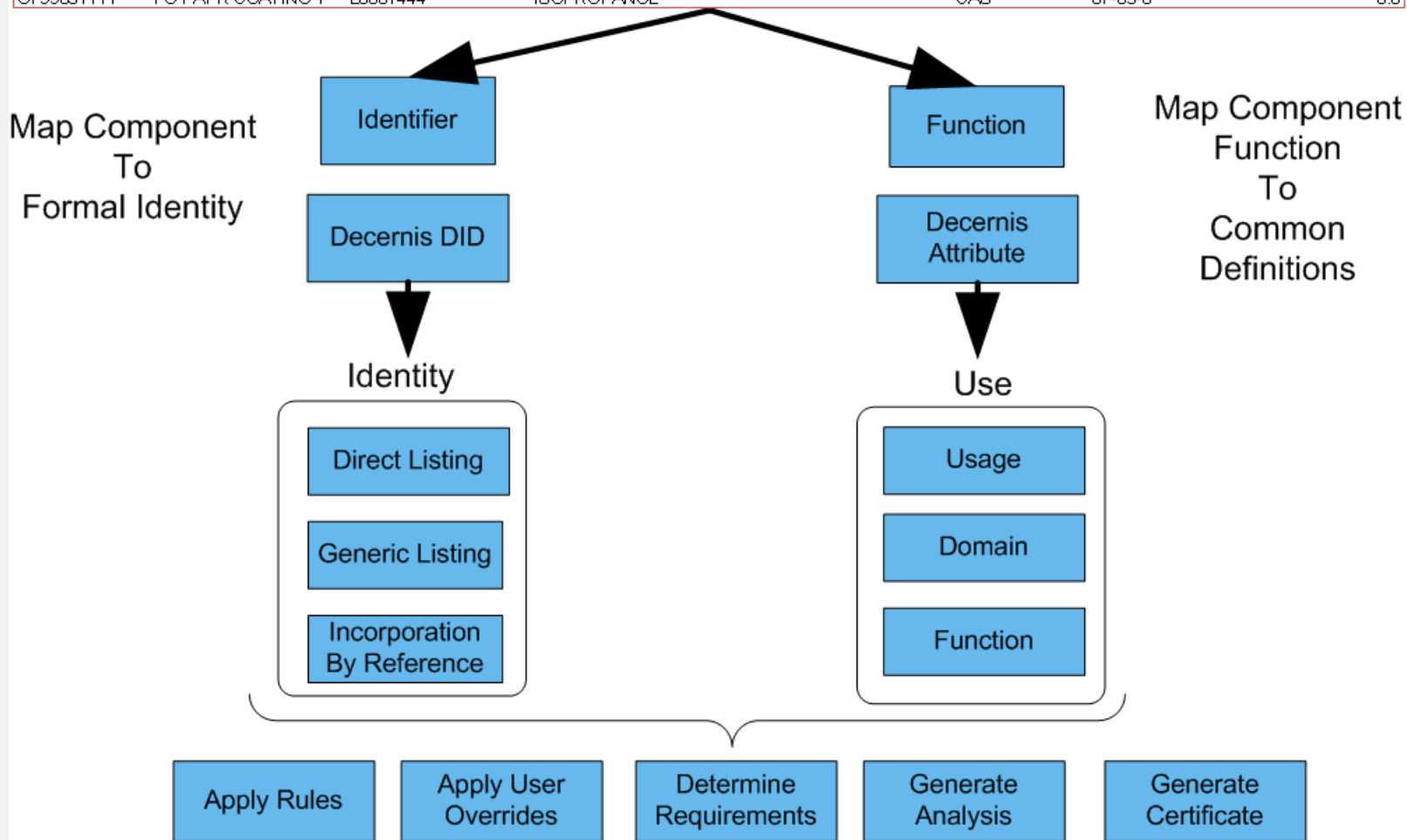
Listes positive & negative, Seuils, LMS ...

dans un format compréhensible avec un ordinateur
y compris ... pour des réglementations mal écrites!

Challenge:

Determiner le Statut Règlementaire d'une Formulation

PROD SPEC	PROD NAME	SUBS SPEC	SUBS NAME	SUBS IDENT	IDENT VALUE	SUBS PERCENT
GF99851111	FG PAPER COATING 1	L0000792	DIMETHYL SILICONES AND SILOXANES	CAS	63148-62-9	66.0
GF99851111	FG PAPER COATING 1	L0311434	SOYBEAN OIL, REFINED & BLEACHED	CAS	8001-22-7	27.2
GF99851111	FG PAPER COATING 1	L0311637	SILICA COLLOIDAL	CAS	112926-00-8	5.2
GF99851111	FG PAPER COATING 1	L157974	SOY BEAN OIL EPOXIDIZED	CAS	8013-07-8	5.1
GF99851111	FG PAPER COATING 1	L098944	CASTOR OIL	CAS	8001-79-4	1.1
GF99851111	FG PAPER COATING 1	L0292353	SILOXANES AND SILICONES, DI-ME, 3-HYDROXY PFC	CAS	68937-55-3	0.4
GF99851111	FG PAPER COATING 1	L0378643	OXIRANE, METHYL-, POLYMER WITH OXIRANE, MCC	CAS	9041-33-2	0.2
GF99851111	FG PAPER COATING 1	L166108	GLYCERINE	CAS	56-81-5	0.1
GF99851111	FG PAPER COATING 1	L0315879	OXIRANE, METHYL-, POLYMER WITH OXIRANE	CAS	9003-11-6	0.0
GF99851111	FG PAPER COATING 1	L0001444	ISOPROPANOL	CAS	67-63-0	0.0





Certificat de Conformité

CERTIFICATION

Product FG PAPER COATING 1
Author Decernis
Date 07 September 2011

We confirm that the product referenced above complies with the following requirements:

Food Contact

China

Listed on GB9685-2008 Hygienic Standards for Users of Additives in Food Container and Packaging Materials

European Union

Complies with Directive 2004/42/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products

Complies with the Regulation (EU) 10/2011

Germany

Complies with German BfR Recommendation XXXVI Paper and board for food contact

United States

Complies with CONEG Model Toxics Legislation

Complies with the requirements of 21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Complies with the requirements of 21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Complies with the requirements of 21 CFR 176.180 Components of paper and paperboard in contact with dry food.

General

European Union

Complies with Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Complies with European Standard EN 71-3 Safety of Toys, Part 3: Migration of certain elements

Decernis, to the best of its knowledge, believes that the information provided above is accurate and correct, based on the sources available at the time of writing.



Challenge : Gestion du Changement

Nombreux changements --> Besoin de revoir le Certificat

• Composition

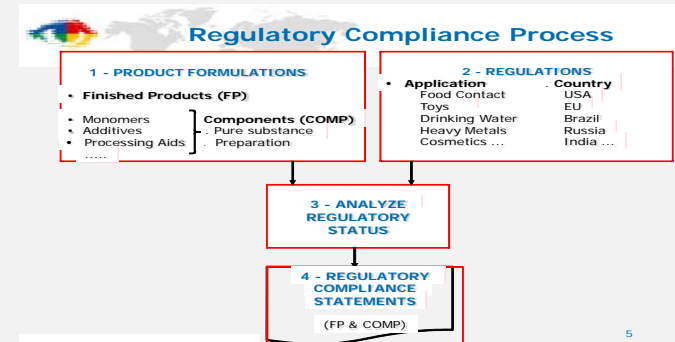
- Reformulation (different pourcentages)
- Nouveau composant ou matière première
- Nouveau fournisseur (matière première existante)

• Règlementation

- Amendement: seuil admissible, liste positive ou négative
- Nouvelle règlementation

• Marché

- Nouveau pays (et règlementations)
- Nouvelle application " "
- Nouveau client avec demande spécifique

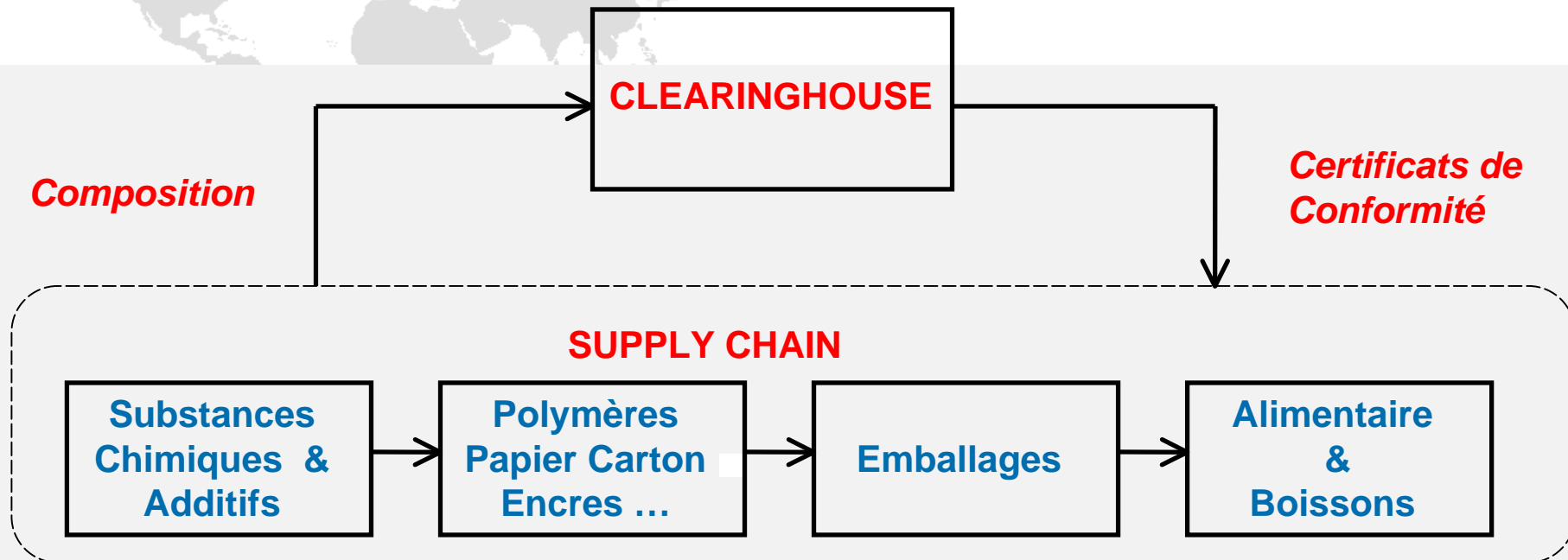




Tendances

- **Complexité croissante des réglementations à travers le monde**
- **Changements de plus en plus fréquents**
- **Complexité croissante des normes d'approvisionnement**
- **Vers une génération systématique des certificats de conformité**
- **Besoin: Bonnes pratiques industrielles et approche commune pour simplifier les transactions sur la Supply chain.**

Vision



Vision pour l'industrie: une Clearinghouse qui recevrait les compositions confidentielles des produits des différents acteurs de la supply chain et publierait des certificats de conformité.



Démonstration

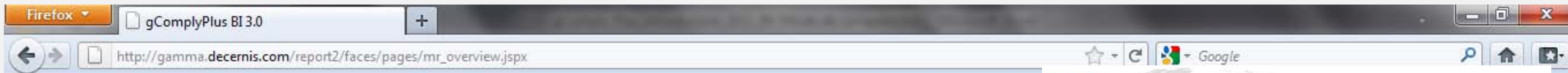
Génération d'un Certificat d'Alimentarité





Une Solution Informatique

en support du Processus Conformité



1 - COMPOSITION PRODUIT

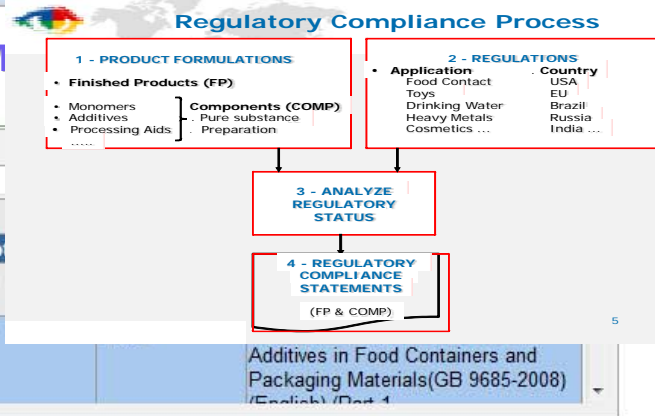
Search:

<input checked="" type="checkbox"/>	Product	Sub-Product	Substance	ID Type	ID Value
<input checked="" type="checkbox"/>	FG PAPER COATING 1		DIMETHYL SILICONES AND SILOXANES	CAS	63148-62-9
<input checked="" type="checkbox"/>	FG PAPER COATING 1		SOYBEAN OIL, REFINED &	CAS	8001-22-7

2 - REGLEM

Template Group: Food Contact

Template	Description
Paper and Paper Board	Pilot Template
Paper and Paper Board	Pilot Template



Run

3 - STATUT REGLEMENTAIRE

Matrix Report | Product Summary | Product Statement

All	Product Name	Substance Name	Identifier Type	Identify Value	21CFR176.170 Result	21CFR176.170 Status	EU 10/2011 Result	EU 10/2011 Status	BFR XXXVI Result	BFR XXXVI Status
<input type="checkbox"/>	FG PAPER COATING 1	CASTOR OIL	CAS	8001-79-4	Review	Complies: Incorporated by reference	Accepted	Complies with the Regulation (EU) 10/2011		
<input type="checkbox"/>	FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CAS	63148-62-9	Review	Complies: Incorporated by reference	Accepted	Complies with the Regulation (EU)		

Review dropdown menu options: Accepted by user, Reset by user, Accepted, Complies: GRAS, Review

4 - CERTIFICAT de CONFORMITE

1 - Composition



gComplyPlus 3.0 Global Compliance
(U.S. Patent 7,769,712 B2)

Regulatory Analysis and Reporting | Logout | Refresh

Analysis and Report Help

Search: Product Name *paper*

<input checked="" type="checkbox"/>	Product	Sub-Product	Prod Key	Substance	Subs Key	ID Type	ID Value	Percent	Attribute
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	DIMETHYL SILICONES AND SILOXANES	L0000792	CAS	63148-62-9	66	Release agent
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	SOYBEAN OIL, REFINED & BLEACHED	L0311434	CAS	8001-22-7	27.2	Pigment binder
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	SILICA COLLOIDAL	L0311637	CAS	112926-00-8	5.2	Pigment
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	SOY BEAN OIL EPOXIDIZED	L157974	CAS	8013-07-8	5.1	Pigment binder
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	CASTOR OIL	L098944	CAS	8001-79-4	1.1	Wetting agent
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	SILOXANES AND SILICONES, DI-ME, 3-HYDROXYPROPYL M	L0292353	CAS	68937-55-3	0.4	Release agent
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	OXIRANE, METHYL-, POLYMER WITH OXIRANE, MONO-2-PR	L0378643	CAS	9041-33-2	0.2	Antimicrobial agent
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	GLYCERINE	L166108	CAS	56-81-5	0.1	Wetting agent
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	OXIRANE, METHYL-, POLYMER WITH OXIRANE	L0315879	CAS	9003-11-6	0.0127	Antimicrobial agent
<input checked="" type="checkbox"/>	FG PAPER COATING 1		GF99851111	ISOPROPANOL	L0001444	CAS	67-63-0	0.0042	Defoaming agent



2- Règlements



gComplyPlus 3.0 Global Compliance
(U.S. Patent 7,769,712 B2)

Regulatory Analysis and Reporting

Logout Refresh

Analysis and Report Help

Template Group: Food Contact ID: Paper and Paper Board

			Materials(GB 9685-2008)(English) (Part 3)
Paper and Paper Board	Pilot Template	China	"Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials(GB 9685-2008)(English) (Part 2
Paper and Paper Board	Pilot Template	China	"Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials(GB 9685-2008)(English) (Part 1
Paper and Paper Board	Pilot Template	European Union	Regulation (EU) No 10/2011 on plastic materials - Annex 3: Food simulants
Paper and Paper Board	Pilot Template	European Union	Regulation (EU) No 10/2011 on plastic materials - Annex 2: Restrictions on materials and articles
Paper and Paper Board	Pilot Template	European Union	Regulation (EU) No 10/2011 on plastic materials - Annex 1: Union list of authorised substances (monomers
Paper and Paper Board	Pilot Template	European Union	Regulation (EU) No 10/2011 on plastic materials - Annex 1: Union list of authorised substances (monomers
Paper and Paper Board	Pilot Template	European Union	Regulation (EU) No 10/2011 on plastic materials - Annex 1: Union list of authorised substances (monomers
Paper and Paper Board	Pilot Template	European Union	EU RoHS Directive 2002/95
Paper and Paper Board	Pilot Template	European Union	Directive 2002/72/EC (Consolidated-2009-11-09): Plastic materials and articles intended to come into contact with foodstuffs - Annex V Specifications
Paper and Paper Board	Pilot Template	European Union	Directive 2002/72/EC (Consolidated-2009-11-09): Plastic materials and articles intended to come into contact with foodstuffs - Annex IVa Lipophilic substances for which the fdf applies
Paper and Paper Board	Pilot Template	European Union	Directive 2002/72/EC (Consolidated-2009-11-09): Plastic materials and

3.1 – Statut Règlementaire (Composants)

Firefox | gComplyPlus BI 3.0 | http://gamma.decernis.com/report2/faces/pages/mr_overview.jspx | Google



gComplyPlus 3.0 Global Compliance
(U.S. Patent 7,769,712 B2)

Regulatory Analysis and Reporting | Logout

Analysis and Rep

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Matrix Report | Product Summary | Product Statement

All	Product Name	Substance Name	Identifier Type	Identify Value	21CFR176.170 Result	21CFR176.170 Status	21CFR176.180 Result	21CFR176.180 Status	EU 10/2011 Result	EU 10/2011 Status	BFR XXXVI Result	BFR XXXVI Status
...	FG PAPER COATING 1	CASTOR OIL	CAS	8001-79-4	Review	Complies: Incorporated by reference	Review	Complies: Incorporated by reference	Accepted	Complies with the Regulation (EU) 10/2011	Accepted by user	
...	FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CAS	63148-62-9	Review	Complies: Incorporated by reference	Review	Complies: Incorporated by reference	Accepted	Complies with the Regulation (EU) 10/2011		
...	FG PAPER COATING 1	GLYCERINE	CAS	56-81-5	Complies: GRAS	Complies: Incorporated by reference	Complies: GRAS	Complies: Incorporated by reference	Accepted	Complies with the Regulation (EU) 10/2011	Accepted	Complies with German BfR Recommendation XXXVI Paper board for food contact
...	FG PAPER	ISOPROPANOL	CAS	67-63-0	Complies: GRAS	Complies: Incorporated	Accepted	Listed	Accepted	Complies with the		



Détail Composant

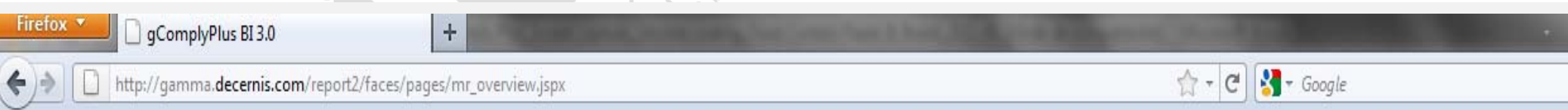
Detail Information - Mozilla Firefox



http://gamma.decernis.com/report2/faces/_ADFv_?_afPfm=-9xznc51hq&t=fred&_vir=/pages/mr/reportDetail.jspx&loc=fr&_minWidth=1024&_minHeight=768&_rtrnId=0

Product Name	Substance Name	Column Name	Display	Comments Usage
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CFR_176_170_RESULT	21 CFR 176.200 Defoaming agents used in coatings	
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CFR_176_170_RESULT	21 CFR 176.210 Defoaming agents used in the manufacture of paper and paperboard	
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CFR_176_170_RESULT	United States 21cfr06 Food Contact Prior Sanction	
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CFR_176_180_RESULT	21 CFR 176.200 Defoaming agents used in coatings	
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CFR_176_180_RESULT	21 CFR 176.210 Defoaming agents used in the manufacture of paper and paperboard	
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CFR_176_180_RESULT	United States 21cfr06 Food Contact Prior Sanction	
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	EU 10/2011 Result	Regulation (EU) No 10/2011 on plastic materials - Annex 1: Union list of authorised substances (monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids) - Table 1	Listed
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	CN_9685_RESULT	Listed: Review usage Limitations	
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	EU_ROHS_RESULT	EU RoHS Directive 2002/95	
FG PAPER COATING 1	DIMETHYL SILICONES AND SILOXANES	EN71_RESULT	EU - DIN EN 71-3 Safety of Toys	

3.2 – Statut Règlementaire (Produit Fini)



gComplyPlus 3.0 Global Compliance
(U.S. Patent 7,769,712 B2)

Regulatory Analysis and Reporting | Logout

Analysis and Re

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Matrix Report Product Summary Product Statement

All	Product Name	Substance Name	Identifier Type	Identify Value	21CFR176.170 Result	21CFR176.180 Result	21CFR176.180 Basis	EU 10/2011 Result	BFR XXXVI Result	CN 9685 Result	CH VOC Result
	FG PAPER COATING 1				Review	Review		Accepted by user			

- Accepted by user
- Reset by user
- Accepted



4.1- Rapport Composants

FOOD CONTACT - Paper and Paper Board

Product Components	Component Identifier	Identifier	Input Percent	Country	Regulation	Status
CASTOR OIL	CAS	8001-79-4	1.1	China	Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials(GB 9685-2008)(English) (Part 3, pp. 79-114)	Review Limitations
CASTOR OIL	CAS	8001-79-4	1.1	European Union	Regulation (EU) No 10/2011 on plastic materials - Annex 1: Union list of authorised substances (monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids) - Table 1	Listed
CASTOR OIL	CAS	8001-79-4	1.1	United States	21 CFR 175.105 Adhesives (2007)	Complies: Incorporated by reference
CASTOR OIL	CAS	8001-79-4	1.1	United States	21 CFR 176.210 Defoaming agents used in the manufacture of paper and paperboard	Complies: Incorporated by reference
DIMETHYL SILICONES AND SILOXANES	CAS	63148-62-966		China	Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials(GB 9685-2008)(English) (Part 5, pp. 149-188)	Review Limitations
DIMETHYL SILICONES AND SILOXANES	CAS	63148-62-966		European Union	Regulation (EU) No 10/2011 on plastic materials - Annex 1: Union list of authorised substances (monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids) - Table 1	Listed
DIMETHYL SILICONES AND SILOXANES	CAS	63148-62-966		United States	21 CFR 176.200 Defoaming agents used in coatings	Complies: Incorporated by reference
DIMETHYL SILICONES AND SILOXANES	CAS	63148-62-966		United States	21 CFR 176.210 Defoaming agents used in the manufacture of paper and paperboard	Complies: Incorporated by reference
GLYCERINE	CAS	56-81-5	.1	China	Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials(GB 9685-2008)(English) (Part 3, pp. 79-114)	Review Limitations
GLYCERINE	CAS	56-81-5	.1	European Union	Regulation (EU) No 10/2011 on plastic materials - Annex 1: Union list of authorised substances (monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and	Listed



4.2 Rapport Produit Fini



DECERNIS
1250 Connecticut Ave. N.W.
Suite 200
Washington, DC 20036

CERTIFICATION

Product FG PAPER COATING 1
Author jdesamauts
Date 16 November 2011

We confirm that the product referenced above complies with the following requirements:

Food Contact

China

This product complies with the GB 9685 Standards

European Union

Complies with the Regulation (EU) 10/2011

Germany

Complies with German BfR Recommendation XXXVI Paper and board for food contact

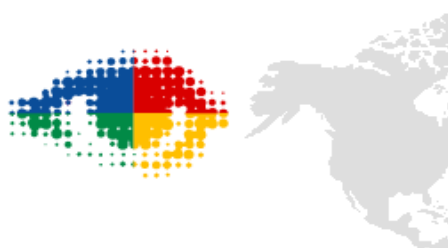
United States

Complies with the requirements of 21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Complies with the requirements of 21 CFR 176.180 Components of paper and paperboard in contact with dry food.

Decernis, to the best of its knowledge, believes that the information provided above is accurate and correct, based on the sources available at the time of writing.

Decernis does not assume liability for the use of the information or claims or damages from any third party.



化学物質の審査及び製造等の規制に関する法律に係る
輸入化学物質の確認書
(Certificate of imported chemical according to the law concerning
examination and regulation of manufacture etc.)

2011年 09 月 17 日
(September 17, 2011)

税関長殿
(Custom)

氏名又は名称及び法人にあつては、その代表者の氏名 印(Stamp)
(Author: name, company name or name of the representative)
住所 (Address)

化学物質名称 (Product name)
FG PAPER COATING 1

上記の参照される化学物質は、下記の要件に準拠していることを確認します。
(We confirm that the product referenced above complies with the following requirements)

Inventory

Australia

すべての製品構成分子は、オーストラリア既存化学物質台帳 (AICS) に記載され、あるいは記載要件が免除される

Canada

すべての製品構成分子は、カナダ国内物質リスト (DSL) に記載され、あるいは記載要件が免除される

China

すべての製品構成分子は、中国現有化学物質名録 (IECSC) に記載され、あるいは記載要件が免除される

European Union

最低限一つの物質が欧州混載化学物質インベントリに記載されず、あるいはリストから除外されている

Japan

最低限一つの物質が化審法(ENCS)に記載されず、あるいはリストから除外されている

Korea

すべての製品構成分子は、韓国既存化学物質目録 (KECI) に記載され、あるいは記載要件が免除される

United States

最低限一つの物質が米国TSCA(有害物質規制法)インベントリーに記載されず、あるいはリストから除外されている