

ASSESSMENT REPORT PROPOSAL IN COMPLIANCE WITH REACH

NO. RC-RC-010-0900101

DATE: Apr. 23, 2009

We have been commissioned by the client to conduct REACH compliance assessment on their products (Contract No.: RC-RC-010-0900101). We have assessed the situation of our client's product under the European Regulation 1907/2006(EC) (hereinafter referred as REACH Regulation), including product categories, substances list, SVHC (Substances of Very High Concern) and also of our client's responsibilities and obligations for this product under REACH Regulation. The result and findings of the assessment and our proposals are described as follows:

1. Client's Information

Name:	Shangyu City Liaoyuan Lighting Electric Appliance Factory
Address :	Lihai Town, Shangyu City, Zhejiang Province, P.R. China
Name of the contact person:	Jianyang Li
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2. Product Identification

Product name:	Energy saving lamps Tube, UV Tubes
Type/ model:	PL5W, PL7W, PL9W, PL11W, PL13W, PL18W, PL24W, PL36W, PL55W/PLC7W, PLC10W, PLC13W, PLC18W, PLC26W/PLT13W, PLT18W, PLT26W, PLT32W, PLT42W/UVA5W, UVA7W, UVA9W, UVA11W, UVA13W, UVA18W, UVA24W, UVA36W, UVA55W/ UVC5W, UVC7W, UVC9W, UVC11W, UVC13W, UVC18W, UVC24W, UVC36W, UVC55W
Physical appearance / color/ odor:	Solid/white /odorless
Product type:	Article

3. Product Substances Information

3.1 Substance on its own or in preparations

Index	Substance name	CAS No.	EC No.	Tone
N/A	N/A	N/A	N/A	N/A

3.2 Substance in article intended to released

Index	Substance name	CAS No.	EC No.	Tone
N/A	N/A	N/A	N/A	N/A

3.3 SVHC (Substance of Very High Concern) in article (Details see Annex 1)

4. Responsibilities and Obligations (related laws and regulations see Annex 2)

4.1 Registration

4.1.1 According to the definition in Article 3(3), Chapter 2, Title I, the client's product, Energy saving lamps Tube/UV Tubes are regarded as "Article".

4.1.2 And according to Article 7(1), Chapter 2, Title 2, there is no substance intended to be released under normal or reasonably foreseeable conditions of use in the client's product. Therefore, registration is not required.

4.2 Notification

4.2.1 As some SVHCs defined in Article 57 of REACH regulation in the client's product glass tube Diarsenic trioxide, capacitance DBP exceed the limitation of a concentration of 0.1 % weight by weight (w/w) (details see annex 1), if one (or more) of these substances is present in quantities totalling over 1 tonne per year per company, EU and EEA producers or importers of this product have to notify ECHA. The notifications have to be submitted not later than 1 June 2011.

Note: This item shall not apply where the importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of this product.

A notification is not required either when the substance has already been registered for that use up the same supply chain or any other supply chain.

4.3 Information Communication Down the Supply Chain

4.3.1 As the concentrations of some SVHCs defined in Article 57 of REACH regulation in the client's product are above 0.1 % weight by weight (w/w) (See details in annex 1), the obligation of communicating information down the supply chain needs to be fulfilled according to Article 33 of REACH Regulation.

4.3.2 From 9 October 2008, EU & EEA suppliers of this product must provide all the information he has, to his customers and, on request, to a consumer within 45 days of the receipt of this request. This information must ensure safe use of this product and, and as a minimum it must include the name of the SVHC.

4.4 Others

4.4.1 Authorisation

Since the manufacture of this product is based outside the EU, and the lifecycle of related substances outside EU is irrelevant with respect to REACH Regulation, there is no obligation of authorisation

required for our client's product.

4.4.2 Restriction

Title VIII and Annex XVII of REACH Regulation will apply from 1 June 2009, however, our client should follow the restriction conditions outlined in Directive 76/769/EEC before then.

5. Assessment Conclusions

According to the product information provided by our client and related Articles of REACH Regulation, We draw the conclusion that:

The product supplied by the client complies with REACH Regulation as it currently stands, if article 6 "proposal for REACH compliance" in this assessment report is fulfilled.

6. Proposal for REACH Compliance

6.1 The client should provide his recipient of the product with information of SVHCs that are above 0.1% weight by weight (w/w) as soon as possible.

6.2 On request by a consumer, supplier of the product shall provide the consumer with the information of SVHCs that are above 0.1% weight by weight (w/w) freely within 45 days.

6.3 A notification to ECHA may be required on 1 June 2011 at the latest for substances which are present in the product above the concentration of 0.1%w/w and totaling over one tonne per year per company.

6.4 The client should pay constant attention to the SVHCs in the candidate list and fulfill related obligations if necessary. This list may be updated regularly and it is important to monitor any changes to it.

6.5 The client should assure the exported products are consistent with the sample provided to Chemical Inspection & Regulation Service Limited in material, vendors and production process.

Prepared by: _____

Ms. Everest Shi
Regulatory Affairs Specialist

Date: _____

Reviewed by: _____

Mr. Jim Wei
Managing Director

Date: _____

STATEMENT

First: Instruction for the assessment conclusion

The above assessment conclusions that we have made is based on the understanding and analysis of the consignor's product and REACH regulation and only applies to the situation described in the report. This conclusion does not apply to any enterprise or product that fails to meet the description.

As parts of REACH regulation (for example Annex XIV) are still been modifying, the above conclusion only applies to REACH regulation as it currently stands.

This report is only used to assist the consignor to know his own responsibility and obligation under REACH Regulation, and provide the actors in his supply chain with evidence that his products are in compliance with REACH regulation.

The consignor should study this report carefully. If there is any doubt or suggestion, please contact with us and we will do our best to make further explanation or any necessary amendments.

Second: Disclaimer Statement

We undertake no responsibility and no obligation to verify the authenticity of information supplied by the consignor.

The client should assure the exported products are consistent with the sample provided to our company in material, vendors and production process. We can't be held responsible or bear any consequence which may result from differences between the sample products provided to us and the exported products.

We have completed this report with all professional competence, responsibility and reasonable due diligence, however due to the limited approach to the consignor, the products and the market we can't guarantee that the content of the report is fully accurate.

Consignor should make a cautious decision to adopt the assessment conclusion of this report. We assume no liability for any loss incurred as a result of the use of the conclusion.

Third: Privacy statement and others

This report has been completed by us independently. We guarantee that we shall not disclose information in the above report to any third party (except with the express written permission of consignor). We shall assume no responsibility for any loss caused by disclosure of the report.

We suggest that before offering the report the consignor should sign a security agreement with the third party in order to keep the information of consignor and products in the report from disclosure.

Chemical Inspection & Regulation Service Limited

ANNEX 1 TEST RESULTS OF SVHC (SUBSTANCE OF VERY HIGH CONCERNED)

Sample Description:

Name:	Energy saving lamps Tube, UV Tubes
Quantity:	8
Description:	LED Lamp, White box packing
Date of receiving sample:	Apr. 9, 2009
Date of test:	Apr. 9, 2009 – Apr. 20, 2009
Test requested:	Fifteen (15) Substances of Very High Concern (SVHC) analysis. SVHC list is based on the publication by European Chemical Agency (ECHA) on 9 October 2008, regarding regulation (EC) No.1907/2006 concerning the REACH.

1. List of SVHC

NO.	Name	CAS No.	EC No.	REACH Limits (mg/kg)	Classification
1	Anthracene	120-12-7	204-371-1	1000	PBT
2	4,4'- Diaminodiphenylmethane	101-77-9	202-974-4	1000	CMR2
3	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4	1000	vPvB
4	Hexabromocyclododecane	25637-99-4 3194-55-6 (134237-51-7, 134237-50-6, 134237-52-8)	247-148-4	1000	PBT
5	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5	1000	PBT
6	Dibutyl phthalate(DBP)	84-74-2	201-557-4	1000	CMR2
7	Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	204-211-0	1000	CMR2
8	Benzyl butyl phthalate(BBP)	85-68-7	201-622-7	1000	CMR2
9	Cobalt dichloride	7646-79-9	231-589-4	1000	CMR2
10	Bis(tributyltin)oxide	56-35-9	200-268-0	1000	PBT
11	Sodium dichromate, dihydrate	10588-01-9	234-190-3	1000	CMR1
12	Lead hydrogen arsenate	7784-40-9	232-064-2	1000	CMR1,2
13	Diarsenic trioxide	1327-53-3	215-481-4	1000	CMR1
14	Diarsenic pentaoxide	1303-28-2	215-116-9	1000	CMR1
15	Triethyl arsenate	15606-95-8	427-700-2	1000	CMR1

Remarks: classification (defined by 67/548/EEC)

1. PBT: Persistent, Bio-accumulative And Toxic
2. CMR1, 2: Carcinogenic, Mutagenic, and toxic to Reproduction.
3. vPvB: very high persistent, very high Bio-accumulative

2. Test Method:

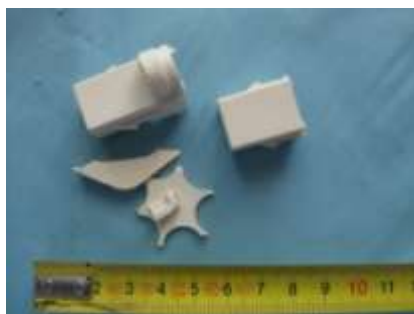
NO.	Item	Screening Methods (ST)		Quantitative Methods (QT)	
		Method	Limits(mg/kg)	Method	Limits(mg/kg)
1	Anthracene	N.A.	N.A.	EPA 8270D	100
2	4,4'-Diaminodiphenylmethane	N.A.	N.A.	EPA 8270D	100
3	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	N.A.	N.A.	EPA 8270D	100
4	Hexabromocyclododecane	EDXRF	200	EPA 8270D	100
5	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	N.A.	N.A.	EPA 8270D	100
6	Dibutyl phthalate(DBP)	N.A.	N.A.	EPA 8270D	100
7	Bis (2-ethyl(hexyl)phthalate) (DEHP)	N.A.	N.A.	EPA 8270D	100
8	Benzyl butyl phthalate(BBP)	N.A.	N.A.	EPA 8270D	100
9	Cobalt dichloride	EDXRF	200	EPA 3052+6010C	100
10	Bis(tributyltin)oxide	EDXRF	200	EPA 8270D	100
11	Sodium dichromate, dihydrate	EDXRF	200	EPA 3060A+7196 A	100
12	Lead hydrogen arsenate	EDXRF	200	EPA 3052+6010C	100
13	Diarsenic trioxide	EDXRF	200	EPA 3052+6010C	100
14	Diarsenic pentaoxide	EDXRF	200	EPA 3052+6010C	100
15	Triethyl arsenate	EDXRF	200	EPA 8270D	100

Remarks:

1. N.A.: Not Applicable.
2. EDXRF: X-ray fluorescence spectrometry.

3. Parts and Photos :

No.	Parts No.	Parts Name
1	0900101-1	Plastic lamp holder(beige and white)
2	0900101-2	Aluminum metal for lamp holder
3	0900101-3	Glass tube
4	0900101-4	Mastic for lamp holder(yellow and white)
5	0900101-5	Metal pins
6	0900101-6	Filament(tungsten filament, molybdenum filament)
7	0900101-7	Capacitance
8	0900101-8	Corrugated paper(white, yellow, green)



0900101-1-1



0900101-1-2



0900101-2



0900101-3



0900101-4-1



0900101-4-2



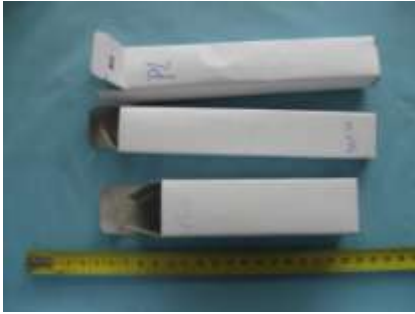
0900101-5



0900101-6



0900101-7



0900101-8-1



0900101-8-2



0900101-8-3



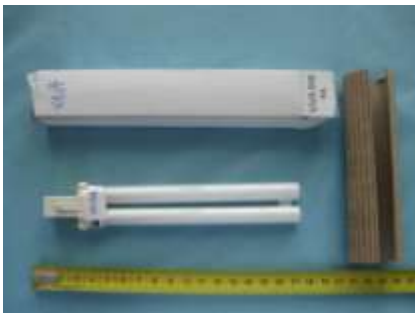
Energy saving lamps –PLT



PLC



PL



VVA

4. Test results:

Test Item	Results (mg/kg)			
	0900101-1	0900101-2	0900101-3	0900101-4
Anthracene	N.D.(QT)	N.T.	N.T.	N.D.(QT)
4,4'- Diaminodiphenylmethane	N.D.(QT)	N.T.	N.T.	N.D.(QT)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	N.D.(QT)	N.T.	N.T.	N.D.(QT)
Hexabromocyclododecane	N.D.(QT)	N.T.	N.T.	N.D.(QT)
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	N.D.(QT)	N.T.	N.T.	N.D.(QT)
Dibutyl phthalate(DBP)	N.D.(QT)	N.T.	N.T.	N.D.(QT)
Bis (2-ethyl(hexyl)phthalate) (DEHP)	N.D.(QT)	N.T.	N.T.	N.D.(QT)
Benzyl butyl phthalate(BBP)	N.D.(QT)	N.T.	N.T.	N.D.(QT)
Cobalt dichloride	N.D.(QT)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Bis(tributyltin)oxide	N.D.(QT)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Sodium dichromate, dihydrate	448	N.D.(ST)	N.D.(QT)	N.D.(QT)
Lead hydrogen arsenate	N.D.(QT)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Diarsenic trioxide	125	N.D.(ST)	2300	N.D.(QT)
Diarsenic pentaoxide	145	N.D.(ST)	N.D.(QT)	N.D.(QT)
Triethyl arsenate	284	N.D.(ST)	N.D.(QT)	N.D.(QT)

Remarks:

1. N.D. = Not detected (<MDL) MDL= Method test limits

N.T. = Not test. According to our assessment, we think that this substance can't exist in the samples under its reasonable and legal usages.

2. ST = Screening Test

3. QT = Qualitative and Quantitative Test

Test Item	Results (mg/kg)			
	0900101-5	0900101-6	0900101-7	0900101-8
Anthracene	N.T.	N.T.	N.D.(QT)	N.D.(QT)
4,4'- Diaminodiphenylmethane	N.T.	N.T.	N.D.(QT)	N.D.(QT)
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	N.T.	N.T.	N.D.(QT)	N.D.(QT)
Hexabromocyclododecane	N.T.	N.T.	N.D.(QT)	N.D.(QT)
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	N.T.	N.T.	N.D.(QT)	N.D.(QT)
Dibutyl phthalate(DBP)	N.T.	N.T.	1230	N.D.(QT)
Bis (2-ethyl(hexyl)phthalate) (DEHP)	N.T.	N.T.	N.D.(QT)	N.D.(QT)
Benzyl butyl phthalate(BBP)	N.T.	N.T.	N.D.(QT)	N.D.(QT)
Cobalt dichloride	N.D.(ST)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Bis(tributyltin)oxide	N.D.(ST)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Sodium dichromate, dihydrate	N.D.(ST)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Lead hydrogen arsenate	N.D.(ST)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Diarsenic trioxide	N.D.(ST)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Diarsenic pentaoxide	N.D.(ST)	N.D.(ST)	N.D.(QT)	N.D.(QT)
Triethyl arsenate	N.D.(ST)	N.D.(ST)	N.D.(QT)	N.D.(QT)

Remarks:

1. Test parts may be single material or a variety of materials which could not be divided by physical ways. Unless otherwise noted, components of base material, coating metal, coating paint and/or coloring pigment were no longer divided, but tested as one whole.
2. All results are applicable only to the test samples.
3. N.D. = Not detected (<MDL) MDL= Method Detection Limits
N.T. = Not test. According to our assessment, we think that this substance can't exist in the samples under its reasonable and legal usages.
4. Because it is difficult to detect the substances CoCl₂, C₂₄H₅₄O₅Sn₂, Na₂Cr₂H₂O₇, PbAsH₃O₄, As₂O₃, As₂O₅ and Triethyl arsenate via direct tests (but via converting them into detectable elements), we consider that all the relative elements exist in the form of their compounds when having the test.
5. Chemical Inspection & Regulation Service Limited reserves the right of final explanations.

ANNEX 2 OF THE APPLICATION OF LAWS AND REGULATIONS

1. The scope of REACH Regulation

"TITLE I GENERAL ISSUES

Chapter 1 Aims, scope and application

Article 2 Application

5. The provisions of the Titles II, V, VI and VII shall not apply to the extent that a substance is used:

(a) in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products⁴ and the Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001 on the Community code relating to medicinal products for human use.

(b) in food or feeding stuffs in accordance with the Regulation (EC) No 178/2002 including use:

(i) as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC of 21st December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended to human consumption;

(ii) as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production and Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council;

(iii) as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition;

(iv) in animal nutrition within the scope of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition."

6. The provisions of Title IV shall not apply to the following preparations in the finished state, intended for the final user:

(a) Medicinal products for human or veterinary use, within the scope of Regulation (EC) No 726/2004 and Directive 2001/82/EC and as defined in Directive 2001/83/EC;

(b) Cosmetic products as defined in Directive 76/768/EEC;

(c) medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labeling of dangerous substances and preparations which ensure the same level of information provision and protection as Directive 1999/45/EC;

(d) Food or feeding stuffs in accordance with Regulation (EC) No 178/2002 including use:

(i) As a food additive in foodstuffs within the scope of Directive 89/107/EEC;

(ii) As a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;

(iii) As an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003;

(iv) In animal nutrition within the scope of Directive 82/471/EEC.

2. Registration responsibility

“TITLE II REGISTRATION OF SUBSTANCES

Chapter 1 General obligation to register and information requirements

Article 5 No data, no market

Subject to Articles 6, 7, 21 and 23, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

Article 6 General obligation to register substances on their own or in preparations

1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency.”

3. Definition of an article

“TITLE I GENERAL ISSUES

Chapter 2 Definitions and general provision

Article 3 Definitions

3) Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;”

4. Registration and notification obligations for substances in articles

“TITLE II REGISTRATION OF SUBSTANCES

Chapter 1 General obligation to register and information requirements

Article 7 Registration and notification of substances in articles

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

(a) the substance is present in those articles in quantities totaling over 1 tone per producer or importer per year;

(b) the substance is intended to be released under normal or reasonably foreseeable

conditions of use.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.”

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;

(b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4. The information to be notified shall include the following:

(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;

(b) the registration number(s) referred to in Article 20(1), if available;

- (c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
- (d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
- (e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
- (f) the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on.

5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
- (b) the Agency has grounds for suspecting that:
 - (i) the substance is released from the articles, and
 - (ii) the release of the substance from the articles presents a risk to human health or the environment;
- (c) the substance is not subject to paragraph 1.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

7. From 1 June 2011 paragraphs 2, 3 and 4 of this Article shall apply 6 months after a substance is identified in accordance with Article 59(1).

8. Any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133(3)."

5. SVHC

"Article 57 Substances to be included in Annex XIV

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

- (a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;

(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;

(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

(d) Substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) Substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

(f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfill the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.”

6. Information communicated down the supply chain

“TITLE IV INFORMATION IN THE SUPPLY CHAIN

Article 31 Requirements for Safety Data Sheets

1. The supplier of a substance or a preparation must provide the recipient of the substance or preparation with a Safety Data Sheet realized in accordance with the Annex II:

.....

Article 32 Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required

.....

Article 33 Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to

allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.”

7. Authorization

“TITLE VII AUTHORISATION

Chapter 1 Authorization requirement

Article 56 General provisions

1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:

(a) the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorized in accordance with Articles 60 to 64; or

(b) the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorization requirement in Annex XIV itself in accordance with Article 58(2); or

(c) the date referred to in Article 58(1)(c)(i) has not been reached; or

(d) the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorization has not yet been taken; or

(e) in cases where the substance is placed on the market, authorization for that use has been granted to his immediate downstream user.

2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorization granted to an actor up his supply chain for that use.

.....

6. Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations:

(a) for substances referred to in Article 57(d), (e) and (f), below a concentration limit of

0,1 % weight by weight (w/w);

(b) for all other substances, below the lowest of the concentration limits specified in Directive

1999/45/EC or in Annex I to Directive 67/548/EEC which result in the classification of the preparation as dangerous.”

8. Restrictions

“TITLE VIII RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

Chapter 1 General issues

Article 67 General provisions

1. A substance on its own, in a preparation or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVII shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.

2. Paragraph 1 shall not apply to the use of substances in cosmetic products, as defined by Directive 76/768/EEC, with regard to restrictions addressing the risks to human health within the scope of that Directive.

3. Until 1 June 2013, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty.

The Commission shall compile and publish an inventory of these restrictions by 1 June 2009.”

9. Only representative of the Non-EU manufacturers

“TITLE II REGISTRATION OF SUBSTANCES

Chapter 1 General obligation to register and information requirements

Article 8 Only representative of a non-Community manufacturer

1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfill, as his only representative, the obligations on importers under this Title.

2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date

information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.”