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sense and simplicity

Compliance assessment for chemical substance regulations

another view on environmental testing

Poppe Onrust
Director Product Substance Management

Philips Healthcare
October 2012

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Agenda

- Introduction
- Global Substance Regulations
- RoHS, REACH
- Product Substance Data Collection
- Substance Risk Management
- Experiences
- Summary & Conclusions

Philips: a strong diversified industrial group

Who we are

Founded in 1891
Headquartered in Amsterdam, The Netherlands

Sales of €22.6 billion in 2011[1]

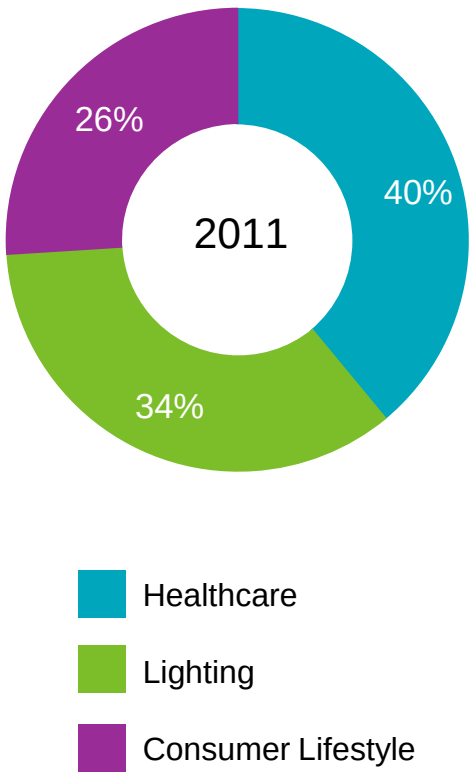
- 33% in Growth Markets
- 65% in B2B
- EBITA 7.4% of sales

Globally recognized brand (world top 50)
Our brand value doubled to $8.7bn since 2004[2]

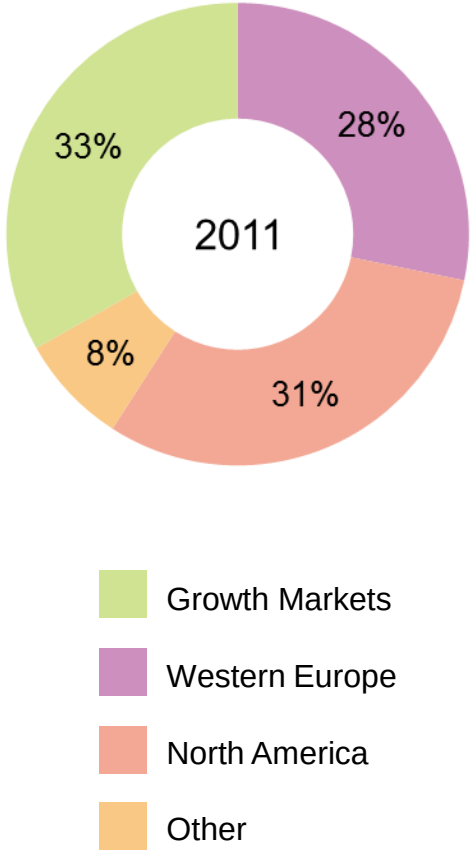
122,000 employees
Sales and service outlets in over 100 countries

€1.6 billion investment in R&D, 7% of sales

Our businesses



Operating in >100 countries



[1]Note - All figures exclude discontinued operations

[2]Source: Interbrand

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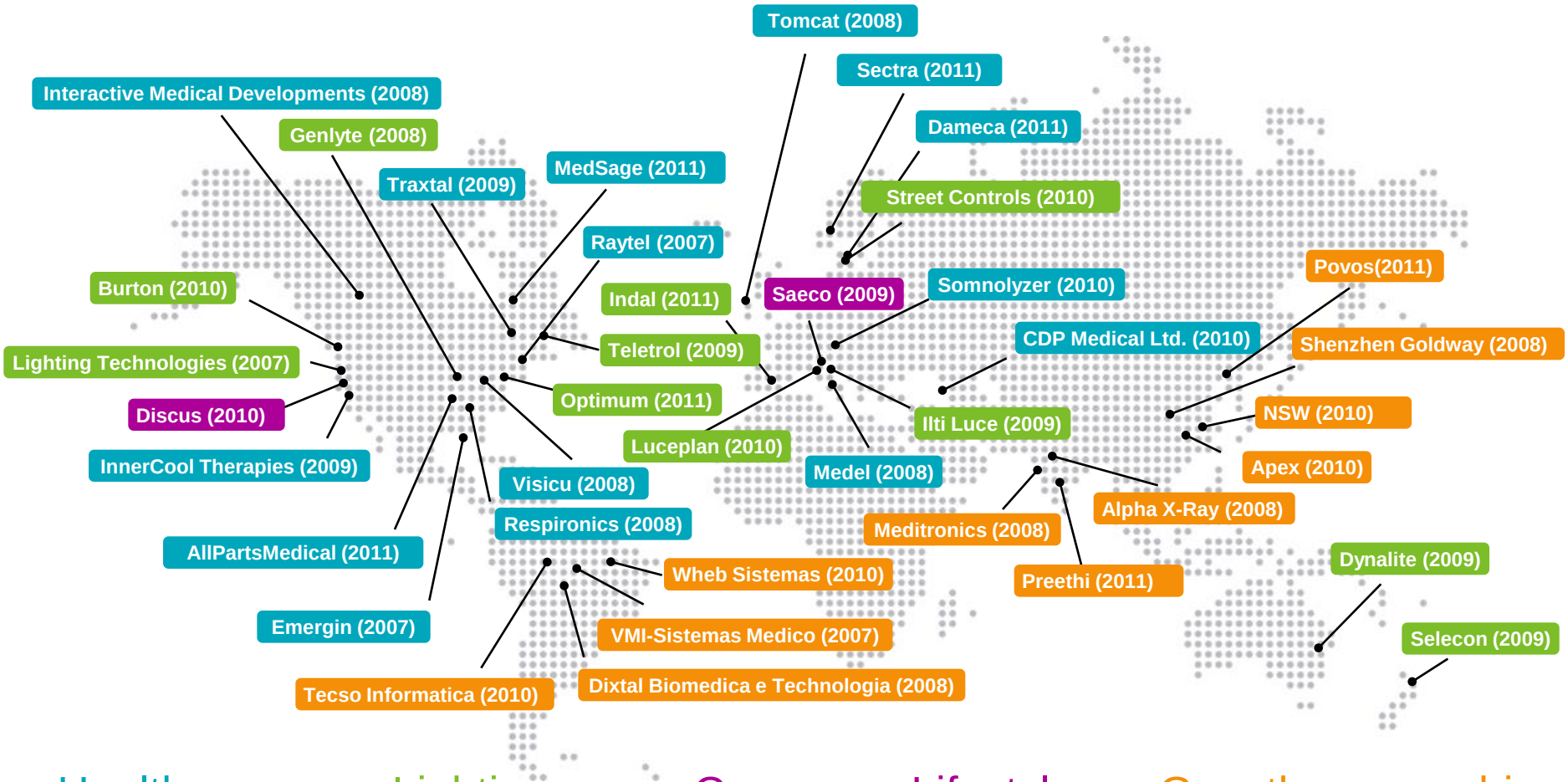
Our global reach

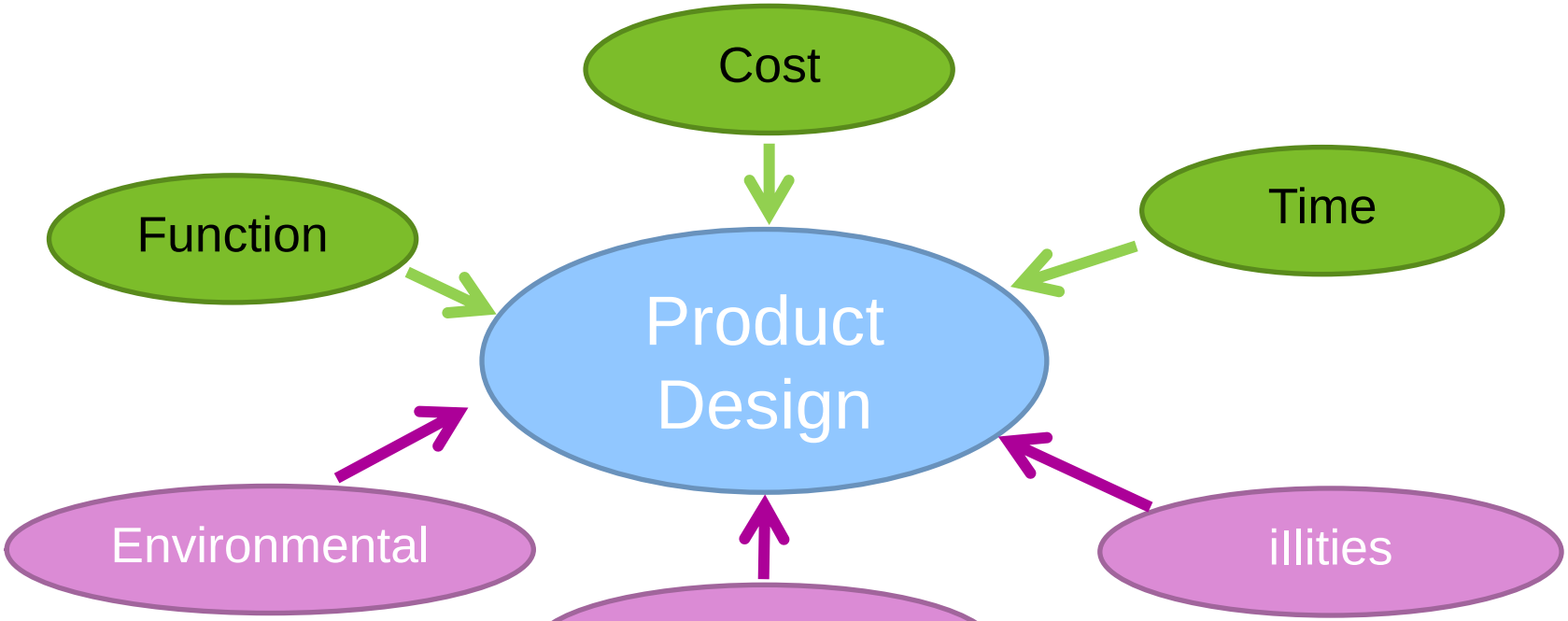
Focused portfolio through strategic acquisitions*



Healthcare Lighting Consumer Lifestyle Growth geographies

* Strategic acquisitions since mid-September 2007 until May 2012

Environmental requirements …



- Humidity
- Temperature
- Chemical
- …

- Machinery Directive
- R&TTE
- MDD
- FDA
- **Environmental**

- Reliability
- Manufacturability
- Serviceability
- Recyclability
- …

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Why Environmental Requirements …

Industry's Responsibility:

> Philips Regulated Substance List

(List of restricted and declarable substances)

http://www.philips.com/about/sustainability/ourenvironment/index.page

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Global Substance Legislation

Legislation is dynamic, yearly new restrictions are added

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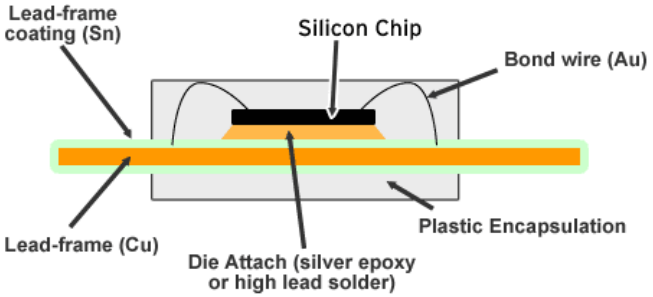
ROHS Directive 2011/65/EU (RoHS-2)
Restriction of Hazardous Substances

- Maximum concentration in any **homogenous material** in the part
  - Cadmium/cadmium compounds : 0.01%
  - Lead/lead compounds : 0.1%
  - Hexavalent chromium compounds : 0.1%
  - Mercury/mercury compounds: 0.1%
  - Polybrominated biphenyls (PBB): 0.1%
  - Polybrominated diphenyl ethers (PBDE): 0.1%



- Exemptions in RoHS2 Directive
  - Annex III exemptions applicable to parts used in any equipment
  - Annex IV exemptions only applicable to parts which are exclusively used in Medical Devices (Cat. 8) and/or Monitoring and Control Instruments (Cat. 9)

- It is a CE Marking Directive
  - CE DoC also must include compliance to this Directive

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ROHS 2011/65/EU (RoHS-2)

Scope

Categories - Annex I

1. Large household appliances.
2. Small household appliances.
3. IT and telecommunications equipment.
4. Consumer equipment.
5. Lighting equipment.
6. Electrical and electronic tools.
7. Toys, leisure and sports equipment.
8. Medical devices **(July 2014)**
9. Monitoring and control instruments including industrial monitoring and control instruments **(July 2017)**
10. Automatic dispensers.
11. Other EEE not covered by any of the categories above.

Out of Scope - Article 1 (4)

(a) equipment … for the security of Member States, including arms, munitions and war material intended for specifically military purposes;

(b) equipment designed to be sent into space;

(c) equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfill its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;

(d) large-scale stationary industrial tools;

(e) large-scale fixed installations;

(f) means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;

(g) non-road mobile machinery made available exclusively for professional use;

(h) active implantable medical devices;

(i) photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;

(j) equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

ROHS 2011/65/EU (RoHS-2)
Requirements for Manufacturers

- Article 7 places new obligations on Manufacturers to **draw up Technical Documentation**, carry out internal production controls, provide EU Declaration of Conformity and affix CE Marking
- **Technical documentation** of internal production controls shall:
  - Specify requirements for product design and manufacture
  - Enable assessment of RoHS conformity for the product
- **Technical documentation** shall, wherever applicable, include:
  - A general description of the product
  - Bill of materials
  - Examinations carried out (i.e. materials assessments, declarations from suppliers etc.)
  - Test reports

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REACH regulation 1907/2006

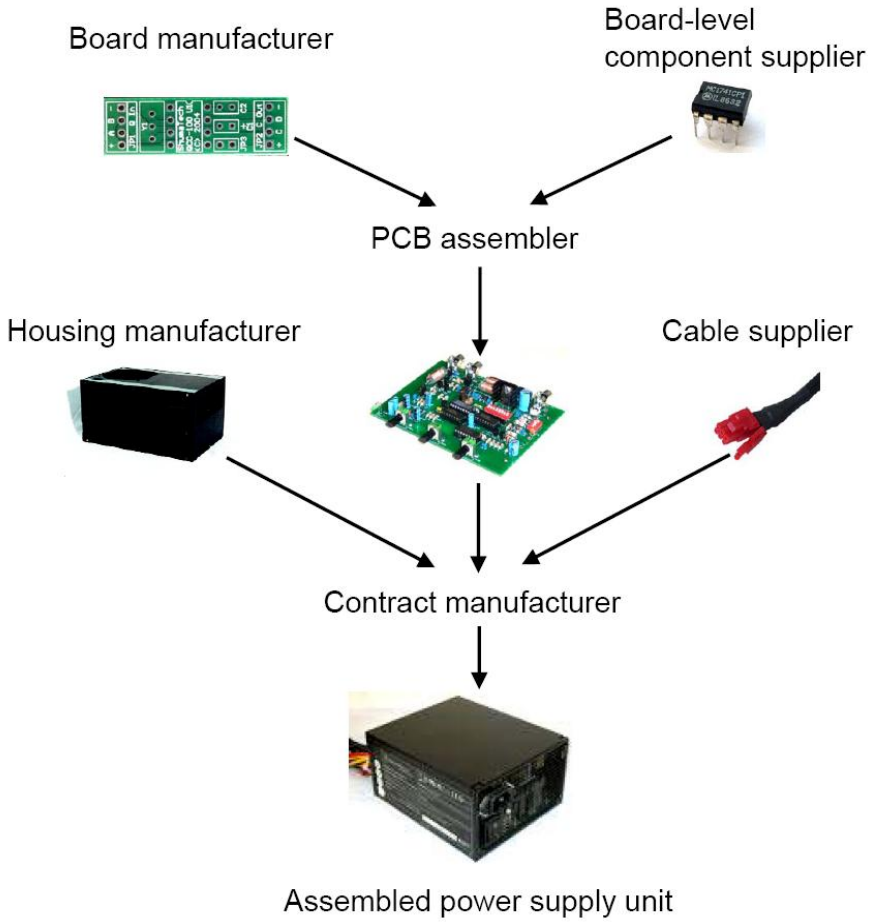
Registration, Evaluation, Authorization and Restriction of Chemicals

- Declare to customers the content of Substances of Very High Concern (SVHC) above 0.1% w/w per article (product) (Article 33)
- Report when imported/exported SVHC's exceed 1 ton per legal entity (Article 7)
- Substance restrictions in EU Directive 76/769/EEC are covered by REACH since June 1 2009 (Article 67)
- 84 SVHC per today (25 may be present in EEE); update ~twice/yr, around 25 new SVHC/yr
- 6 SVHC are recommended for authorization; these will become restricted in 2014 onwards (Annex XIV)

"Whenever standard information from suppliers is not sufficient to check compliance with REACH communication rules, companies have to obtain the necessary information by pro-active requests in the supply chain."

REACH Candidate List Substance Declarations apply to the supplied article

- Article = *"any object which during production is given a special shape, surface or design"*
- All items in this diagram are Articles
- EU supplier must declare if the Article they supply contains any REACH Candidate list Substance > 0.1% w/w of the Article



Collecting data from suppliers
.. costly and time consuming ..

- OEMs ask suppliers to declare against own list of substances
  - Suppliers often don't have chemical knowledge to respond to a list of substance names
  - OEM needs to maintain own knowledge of changing regulations and keep its own list up-to-date
- OEMs use many different collection systems / reporting formats
  - OEM has to build / buy their own collecting system and process
  - OEM has to invest time to train suppliers
  - Supplier has to spend time to learn to use many different systems
  - OEM has to keep own system up-to-date
  - Developed by Quality/Regulatory but work done by Purchasing

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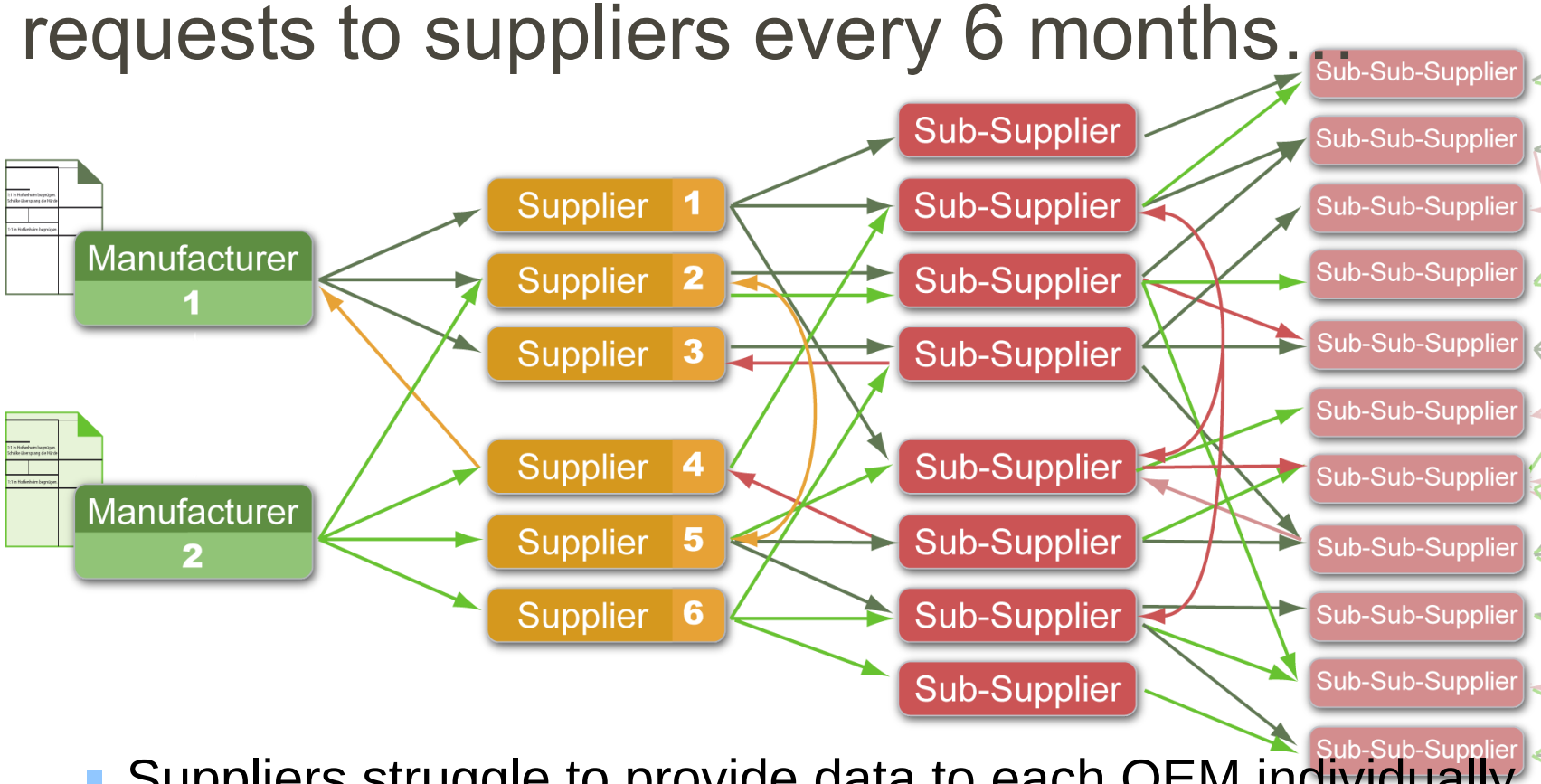
If each OEM builds own database and sends requests to suppliers every 6 months…



- Suppliers struggle to provide data to each OEM individually
  - Poor response rate from suppliers and difficult to get updated data from suppliers every 6 months
  - Poor data quality

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Microsoft Excel
97-2003 Workshee

Example EOM Declaration request

Rev.5E

Inquiry answer sheet (chemical substances)

Supplier code	T0629160000	Company name	INVIVO CORPORATION, A DIVISION OF PHILIPS HEALTHCAR
Organization		Job title	

Prohibited substances	Prohibited substances	Certain Tributyl Tin (TBT) and Triphenyl Tin (TPT) compounds	<Refer to page 18 of theJIG-101A>	1: Contained, 0: Not contained	Regardless of the purpose of use of the substance, provide a reply stating whether or not it is contained.(mandatory)
	Prohibited substances	Polychlorinated Biphenyls (PCBs) and Polychlorinated Terphenyls (PC	<Refer to page 17 of the		Regardless of the purpose of use of the substance, provide a reply stating whether or not it is
	Prohibited substances	Po			pose of use of the substance, provide a reply stating whether or not it is
	Prohibited substances	As			pose of use of the substance, provide a reply stating whether or not it is
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	Prohibited substances	Oz			pose of use of the substance, provide a reply stating whether or not it is
	Prohibited substances	Ra			pose of use of the substance, provide a reply stating whether or not it is
	Prohibited substances/REACH	4,4' -Diaminodiphenylmethane; 4,4' -methylenedianiline	CASNo. 101-77-9	1: Contained, 0: Not contained	Regardless of the purpose of use of the substance, provide a reply stating whether or not it is contained.(mandatory)
				Content (wt%)	When "1" is entered, fill in the percentage [wt%] obtained by calculation with the weight of the entire article set as the denominator.
	Prohibited substances/REACH	Tributyl Tin Oxide (TBTO)	<Refer to page 18 of the JIG-101A>	1: Contained, 0: Not contained	Regardless of the purpose of use of the substance, provide a reply stating whether or not it is contained.(mandatory)
				Content (wt%)	When "1" is entered, fill in the percentage [wt%] obtained by calculation with the weight of the entire article set as the denominator.
	Prohibited substances/REACH	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)			Regardless of the purpose of use of the substance, provide a reply stating whether or not it is
					the percentage [wt%] obtained by calculation with the weight of the ominator.
	REACH	Anthracene	CASNo. 120-12-7		ion result obtained by setting the weight of the entire article as the denominator is equal to or greater than the threshold value (0.1 wt%). Otherwise, enter "0".
				Content (wt%)	When "1" is entered, fill in the percentage [wt%] obtained by calculation with the weight of the entire article set as the denominator.
	REACH	Cobalt dichloride	CASNo. 7646-79-9	1: Contained, 0: Not contained	Enter "1" when the calculation result obtained by setting the weight of the entire article as the denominator is equal to or greater than the threshold value (0.1 wt%). Otherwise, enter "0".
				Content (wt%)	When "1" is entered, fill in the percentage [wt%] obtained by calculation with the weight of the entire article set as the denominator.
	REACH	Sodium dichromate, dihydrate	CASNo. 7789-12-0	1: Contained, 0:	e as the r "0".
				Content	ht of the
	REACH	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	CASNo. 81-15-2	1: Contained, 0: Not contained	Enter "1" when the calculation result obtained by setting the weight of the entire article as the denominator is equal to or greater than the threshold value (0.1 wt%). Otherwise, enter "0".
				Content (wt%)	When "1" is entered, fill in the percentage [wt%] obtained by calculation with the weight of the

All regulated substances are listed in a OEM formatted excel sheet, without any guidance on likelihood presence in products

Must be send back via email

Lot of effort for each supplier and OEM!!

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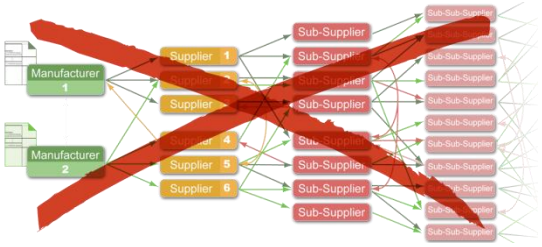
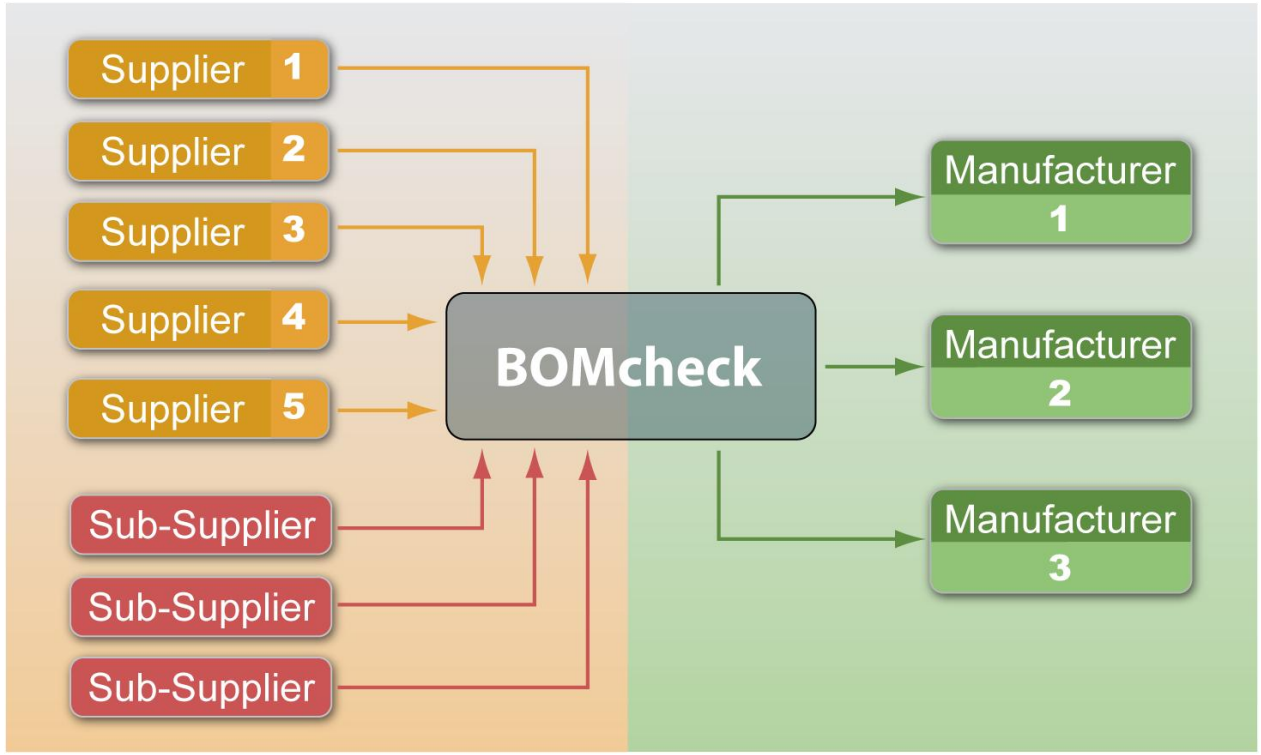
Why not create a centralised database that can be shared by all OEMs?





- ✓ Suppliers save time and costs
- ✓ Manufacturers achieve higher quality data and faster response at lower costs

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Environ - BOMcheck ©

BOMcheck.net

- One industry harmonized list of regulated substances
- One globally shared declaration database
- Guidance on substances: most of our suppliers have little to no knowledge on chemicals > supports easy declaration of products
- Guidance on regulations: always the most actual status of restricted substances which secures access to all world-markets
- Web-based tool, no local IT installation (SAAS)
- Contains full database of chemical substances allowing FMD

>> BOMcheck offers an efficient, effective and low-cost solution to manage substance data

ENVIRON

SAAS: Software as a Service
FMD: Full Material Disclosure

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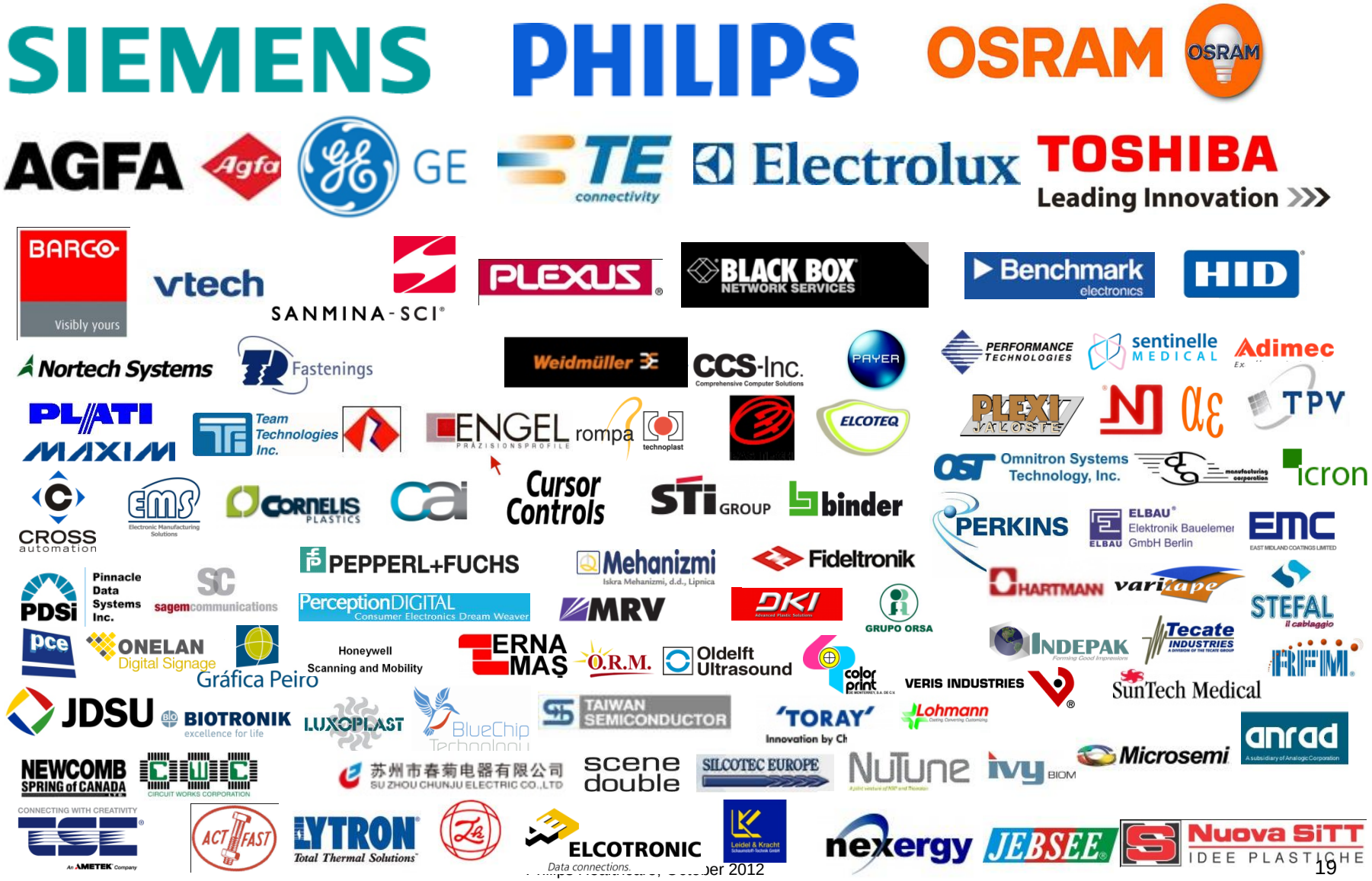
350 OEMs using BOMcheck to manage supplier regulatory compliance (REACH, RoHS, etc)



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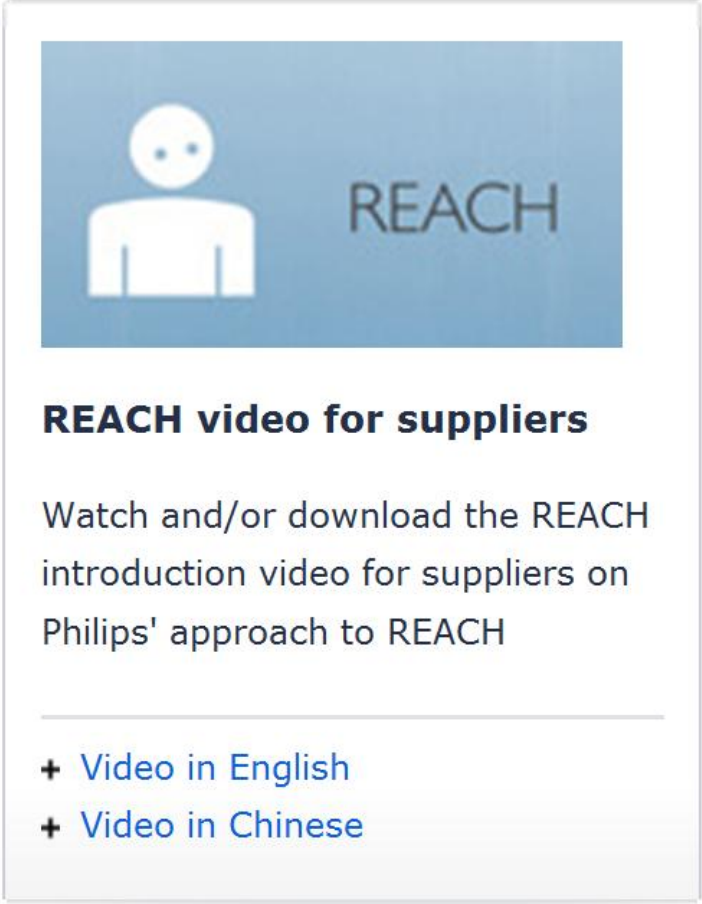
REACH Candidate List requirements to suppliers

- Explained in a 7 minute video
- Available in Chinese and English
- Explains why Philips encourages suppliers to provide FMD

- Link to Philips video

- Similar link to Siemens video



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A long journey …

- Compliance Risk!
  - Supplier roll-out slow
  - Tier 2,3,4.. Components missing

- Strict rules on RoHS technical file (CE) according to Annex II Module A of Decision 768/2008/EC

Conclusion:

- Apply **Product Substance (risk) Management**
  - Risk based declaration process needed
  - Parts / Components materials risks
  - Supplier risks

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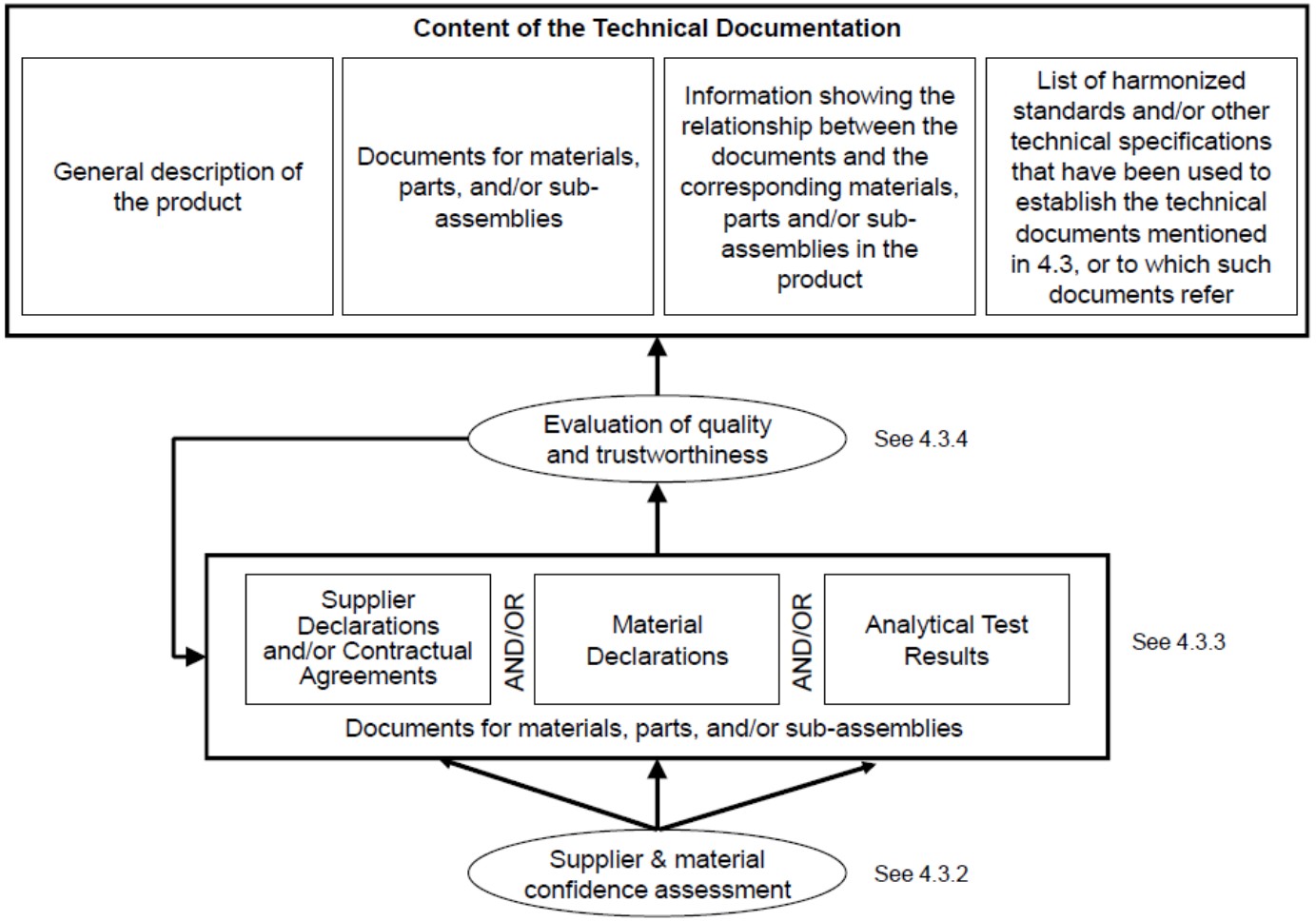
Harmonized Standard EN 50581

Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances



Product Substance Risk Management

Table 1: Identified Option Numbers for Supplier Risk / Product Risk Combination

Supplier Maturity (risk)	**Product Risk**		
	Low	Medium	High
A (low)	1 or 2	2	
B (medium)	1 or 2	2	3a
C (high)	1	3b	

Table 2: Evidence Required per Option Number

Option Number	**Supplier risk / product risk combination** (derived from supplier risk – product risk matrix)	**Evidence**
1	Identification of low risk of regulated substances presence	Self Declaration, template acc. IEC/PAS 62596 table B1[2]
2	Substance declaration by type A supplier for medium/high risk components or Substance declaration by type B supplier and for medium risk component	Supplier Declaration only - no further evidence needed
3a	Substance declaration by type B supplier for high risk component	Supplier Declaration and recent analysis report required
3b	Substance declaration by type C supplier for medium/high risk component	Supplier declaration, recent analysis report required and regular inspection (either at manufacturer site or incoming inspection)

Source: Enforcement Guidance for EU-RoHS

Product Risk		
Low	Medium	High

Product Substance Risk Assessment
Example: REACH SVHC's

- REACH has 84 different substance restrictions (June 2012)
- Eliminate those substance restrictions which are not relevant to materials and parts for use in hardware products and electrical and electronic equipment
- Only focus on those REACH Restricted Substances which can be found in materials and parts for use in hardware products and electrical and electronic equipment

  - *BOMcheck eliminates 59 substance restrictions which are not relevant to materials and parts for use in hardware products and electrical and electronic equipment*

    - BOMcheck Substance List Working Group shares chemical knowledge to decide which Substance Restrictions are not relevant

Product Risk		
Low	Medium	High

Materials at risk of containing remaining REACH Candidate List substances:

- Polyurethane
- Lithium ion batteries
- Plasticisers and flame retardants (e.g. found in plastics, rubber, sealants, adhesives, textiles, etc)
- Humidity indicators (e.g. silica gels which change colour when they absorb water)

- Glass
- High temperature insulating materials
- Biocides (e.g. to prevent mould growth inside polyurethane foam)
- Wood, paper, cotton and other plant-derived materials
- Lead chromates used as yellow and red colorants
  - If part is compliant to RoHS restrictions for lead or chromium then BOMcheck automatically sets these REACH Candidate List Substances to “compliance = Yes”

➢ **Materials and parts that are not listed here do not normally contain REACH Candidate List substances > 0.1% w/w**

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Product Risk		
Low	Medium	High

BOMcheck tool guidance on substance assessment

Are any parts or materials manufactured in a very unusual way? ○ Yes ✗ No

Substance	Likely to be found in hardware and EEE?	What percentage w/w of the substance does the part contain?
	Auto-fill all substances to:	✓ ≤0.1% ✗ >0.1% ? Missing information
Substances used in polyurethane		✓ Part does not contain polyurethane
2,2'-dichloro-4,4'-methylenedianiline, also known as MOCA *Date of publication: 19 December 2011*	Yes. Residual un-reacted MOCA may be present in polyurethane up to 4% w/w.	○ ≤0.1% ○ >0.1% ? Missing information
Substances used in lithium ion batteries		✓ Part for does not contain lithium ion batteries
Bis(2-methoxyethyl) ether, also known as Diglyme *Date of publication: 19 December 2011*	Yes. Diglyme is used as a solvent in battery electrolytes for sealed lithium ion batteries	○ ≤0.1% ○ >0.1% ? Missing information
1,2-bis(2-methoxyethoxy) ethane also known as Triglyme *Date of publication: 18 June 2012*	Yes. Triglyme is used as a solvent in battery electrolytes for sealed lithium ion batteries	○ ≤0.1% ○ >0.1% ? Missing information
1,2-dimethoxyethane, also known as EGDME *Date of publication: 18 June 2012*	Yes. EGDME is used as a solvent in battery electrolytes for sealed lithium ion batteries	○ ≤0.1% ○ >0.1% ? Missing information
Plasticisers and flame retardants		✓ Part does not contain plasticisers or flame retardants
Bis(2-methoxyethyl) phthalate , also known as DMEP *Date of publication: 19 December 2011*	Yes. DMEP, is used as a plasticizer in the production of nitrocellulose, acetyl cellulose, polyvinyl acetate, polyvinyl chloride (PVC) and polyvinylidene chloride	○ ≤0.1% ○ >0.1% ? Missing information

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RoHS / REACH testing

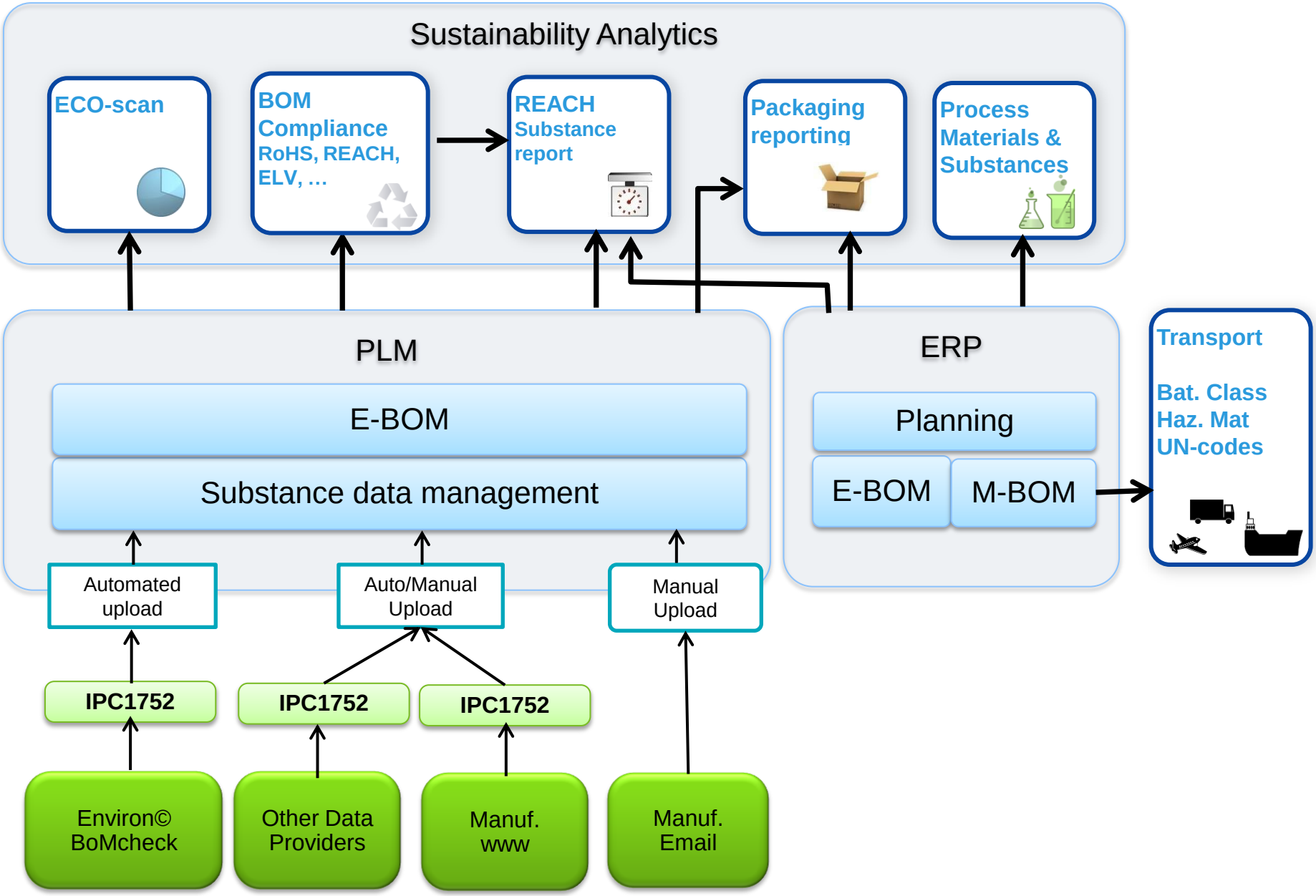
- IEC62321

  Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)

- XRF (RoHS)
  - X-ray fluorescence spectrometry

- Certified testlabs
  - SGS
  - Intertek
  - Philips MiPlaza

PHILIPS Integration with Product Data Management Architecture



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Experiences with suppliers providing declarations

Challenge	Solution
Lack of chemicals knowledge	• Improve BOMcheck guidance to help prioritize relevant substances • Provide Philips specific guidelines for certain materials • Explain for which substances/products we require 3rd party test certificate - depending on risk status of supplier
BOMcheck usage by Suppliers	• Numerous improvements through BOMcheck steering committee together with other OEMs • Philips has more than 90 super users and portal access to manufacturing account of BOMcheck for all supplier account managers, feeding the improvement process • Encourage supplier to comply with Substance Declaration Standard IPC 1752 to allow automated data exchange
Lack of resources	• Emphasizing the importance of legal compliance and advising on the use of third party support (& testing) • Demonstrate through personal training that a smart strategy reduces declaration times to lower levels than paper declarations

Summary & Conclusions

- **Compliance regulations on the restriction of hazardous substances will increasingly impact the materials selection in the design process**
  - Impact on reliability, e.g. PCBA designs
- **Risk assessment for both suppliers and products is needed to focus on data collection which needs high(est) priority**
  - Many products have large BOMs and many tiers which does not allow to define full compliance on a deterministic approach
- **BOMcheck is considered the best industry standard to collect substance management data for OEMs**
  - Platform which allow to share data amongst suppliers and OEMs
  - Providing expert guidance in delivering compliance declarations
  - Supports interface standards to exchange compliance data

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Sustainability as a driver for growth

Accelerating sustainable business

- Green Products represented 39% of total sales in 2011, up from 30% in 2009
- By 2015 Philips aims to invest EUR 2 billion in Green Innovation

EcoVision targets for 2010 – 2015

- Bringing care to more than 500 million people
- Improving the energy efficiency of Philips overall portfolio by 50%
- Doubling the global collection and recycling amounts of our products, as well as double the amount of recycled materials in our products


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