Microfluidic Standardisation Part 2: Testing and characterisation
Outline

- Challenges in the field of microfluidics
- A diversified market
- Lack of Standardisation
- Work till date: Design Guideline for Microfluidic Device and Component Interfaces

Next steps

- Generate Vocabulary, i.e. definitions of properties, components, functions
- List and describe parameters to be tested
- Are there existing Norms that we can refer to?
- Generate protocols for each parameter
- Certification of measuring protocol required?

- Experiences from IMTs facility
Service offering to the Bio Photonics industry

Development and large scale manufacture of cost effective glass consumables

substrate: glass, silicon, hybrid

functionalization: biological, chemical, electronical

detection: integrated, external, optional

OEM component: system integration through customer

flow cell

cover slip with access holes

(integrated) - covalent bonding chemistry

nano-patterning

Micro-channels

nano-wells

nano-pillars

integrated electrodes
Automated process line for 200mm wafers

Glass cleaning  Coating  Resist Coating  Exposure  Wet Process

RIE-cluster  Bonding  Dicing  AOI  Final Cleaning

Flexible Capacity  > 14 - 20’000 wafers/month from 1 to 1Mio. glass chips per month
Segmentation of Microfluidic Applications

- **Clinical and Veterinary Diagnostics**
  Laboratory equipment for clinical and veterinary diagnostics

- **Point-of-Care Diagnostics**
  Out-of-the-lab diagnostic equipment for near-patient testing, intensive care, doctor’s offices, home testing

- **Pharmaceutical and Life Science Research**
  Microfluidic devices for drug discovery and screening, genomics, proteomics, cell analysis...

- **Analytical Devices**
  Microfluidic chips and columns for mass spectrometry, chromatography and HPLC sample preparation

- **Industrial, Environmental and Agro-Food Testing**
  Microfluidic-based tests for quality/process control and water testing (pesticides, bacteria, etc.). Includes military, security and forensics applications

- **Drug delivery**
  Microfluidic devices for drug delivery, such as inhalers, microneedles and implantable micropumps

- **Micro Reaction – Flow Chemistry**
  Microfluidic devices for micro reaction involved in research or in pilot-production units
Challenges of microfluidics

- Each Life Science Application is based on a different Biosensor Technology
- Though same Application, due to patent restrictions different production schemes
- NO Standardisation
- Understanding the needs → translate these into deliverables
- Immense time pressure
  - Multiple iterations
  - rapid prototypes
    - ability to scale-up
  - Cost efficiency
  - Chip design validation & optimization
  - QC referred to existing protocols
Diverse road maps, consumables

No standardisation
Hybridisation of Materials / Technologies

Hybrid solution proposed by IMEC / BE, http://www2.imec.be/be_en/home.html

IMT AG
Hybridisation of Materials / Technologies

Pick & Place equipment

IMT AG
Pacific Biosystems
Veredus Laboratories / STMicroelectronics
# Comparison of Materials

Table 1. Comparison of materials based on mechanical, chemical, and optical properties.

<table>
<thead>
<tr>
<th>Mechanical Properties</th>
<th>SILICON/GLASS(^a)</th>
<th>ELASTOMERS</th>
<th>THERMOSET</th>
<th>THERMOPLASTICS</th>
<th>HYDROGEL</th>
<th>PAPER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Young's (tensile) modulus (GPa)</td>
<td>130–180/50-90</td>
<td>-0.0005</td>
<td>2.0–2.7</td>
<td>1.4–4.1</td>
<td>low</td>
<td>0.0003–0.0025</td>
</tr>
<tr>
<td>Common Technique for Microfabrication</td>
<td>photolithography</td>
<td>casting</td>
<td>casting, photopolymerization</td>
<td>thermomolding</td>
<td>casting, photopolymerization</td>
<td>photolithography, printing</td>
</tr>
<tr>
<td>Smallest Channel Dimension</td>
<td>&lt;100 nm</td>
<td>&lt;1 μm</td>
<td>&lt;100 nm</td>
<td>~100 nm</td>
<td>~10 μm</td>
<td>~200 μm</td>
</tr>
<tr>
<td>Aspect Ratio</td>
<td>limited 3D</td>
<td>3D</td>
<td>arbitrary 3D</td>
<td>3D</td>
<td>3D</td>
<td>2D</td>
</tr>
<tr>
<td>Thermostability</td>
<td>very high</td>
<td>medium</td>
<td>high</td>
<td>medium to high</td>
<td>low</td>
<td>medium</td>
</tr>
<tr>
<td>Chemical Properties</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resistance to Oxidizer</td>
<td>excellent</td>
<td>moderate</td>
<td>good</td>
<td>moderate to good(^b)</td>
<td>low</td>
<td>low</td>
</tr>
<tr>
<td>Solvent Compatibility</td>
<td>very high</td>
<td>low</td>
<td>high</td>
<td>medium to high</td>
<td>low</td>
<td>medium</td>
</tr>
<tr>
<td>Hydrophobicity</td>
<td>hydrophilic</td>
<td>hydrophobic</td>
<td>hydrophobic</td>
<td>hydrophobic</td>
<td>hydrophilic</td>
<td>amphiphilic</td>
</tr>
<tr>
<td>Surface Charge</td>
<td>very stable</td>
<td>not stable</td>
<td>stable</td>
<td>stable</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Permeable to Oxygen (Barrer(^c))</td>
<td>&lt;0.01</td>
<td>~500</td>
<td>0.03–1</td>
<td>0.05–5</td>
<td>&gt;1</td>
<td>&gt;1</td>
</tr>
<tr>
<td>Optical Properties</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Optical Transparency</td>
<td>no/high</td>
<td>high</td>
<td>high</td>
<td>medium to high</td>
<td>low to medium</td>
<td>low</td>
</tr>
<tr>
<td>Auto-fluorescence</td>
<td>no/some</td>
<td>some/high</td>
<td>some/high</td>
<td>some/high</td>
<td>low</td>
<td>high</td>
</tr>
</tbody>
</table>

\(^a\)Photosensitive glass is considered as thermoset.

\(^b\)Excellent for Teflon.

\(^c\)1 Barrer = 10\(^-10\) cm\(^3\) O\(^2\)(STD) cm cm\(^{-2}\) s\(^{-1}\) cmHg\(^{-1}\)

We need standards!
Standardisation mission

- Facilitating the uptake of microfluidics by simplifying the integration of microfluidic components and systems and pushing towards lower costs, shorter time to market and reusability in multiple applications.

- Specifically by:
  - Defining industry wide supported guidelines and standards that will enable reliable microfluidic interconnections and affordable integration,
  - supported by standardized generic validation tests to guarantee fitness for use.
The way till here

MF Consortium discussions 2013-2016
Henne van Herren, White papers
MFManufacturing, European initiative for the standardization and manufacturability of complex micro-fluidic (MF) devices
Towards Standardisation in Microfluidics
- 1st workshop at NIST, Gaithersburg [USA], Dr. Darwin Reyes
- 2nd workshop at imec, Leuven [BE], Dr. Chengxun Liu
ISO AWI 22:916, Interoperability of microfluidic devices -- Guidelines for pitch spacing dimensions and initial device classification, October 13th 2017

Microfluidics Association Charta
NEXT:
- 3rd workshop at CEA-LETI, Grenoble [FR], Dr. Nicolas Verplanck
Microfluidics Association Charta

Mission

The Microfluidics Association exists to encourage the development, coordination, and dissemination of engineering knowledge as well as market and technical information on microfluidics. It provides industry stewardship and engages industrial, academic and government stakeholders to advance the interests of the global Microfluidics Industry Supply Chain.

Vision

The Microfluidics Association promotes the development of the Microfluidics industry supply chain and positively influences the growth and prosperity of its members. The Microfluidics Association advances the mutual business interests of its membership and promotes a free and open global marketplace by defining a common language and definitions and promoting standards thereof.

It will foster the education of people for the purpose of implementing the defined standards and processes and facilitate the growth of the global Microfluidics Industry Supply Chain.
Committee Charters

• Standards Technical Committee
  The Technical Committee coordinates and animates the technical working groups according to the needs as defined by the supply chain. The committee will promote and coordinate the creation of roadmaps.

• Dissemination Committee
  supports the development of event themes and content, assist in identifying and/or recruiting speakers, and related functions as a steering committee, is responsible for dissemination activities like website, and promotes and stimulate education in microfluidics.

• Regional Committees
  Regional advisory boards provide a local forum for the Microfluidics Association members, coordinate the needs and interests of the local members and promotes the interests of the Association towards regional institutions, governmental and other.

• Marketing Data & Lobbying committee
  TBD
Technical Working Groups

Working groups can be initiated by the committees when the need arises and will function as long as needed. Technical Working Groups should make a workplan, priorities activities, provide inputs for the roadmap and contributes to the vocabulary.

The working groups should have a members list, a secretary and a chair who reports to the Technical Committee.

- **Flow Control Working Group**
  
  To explore, evaluate and formulate consensus-based flow control specifications that through voluntary compliance will enhance the manufacturing capability of the microfluidic industry.

- **Testing Methods Working Group**
  
  Proposing testing protocols to be used by the microfluidic community. Preferably by cross referencing to existing norms from neighboring industry segments or, if needed, adapting them. If needed protocols are lacking, the working group should initiate discussions to develop these protocols.

- **Interfacing Working Group**

- **Modularity Working Group**
Interested organisations

Aline
AIT.AC
Alphasip
AMPHASYS
APIX
Axetris
Axxicon Moulds
BlackHole Lab
Blacktrace/Dolomite
Brigham Young University
Bronkhorst
BVT
CEA-Leti
Cellix
CETIAT
CFBI
COATEMA
Corning
Cytomag
Danaher
DCU
Electric Ant Laboratory
Elvesys
EmulTech
enablingMNT
Enplas
EPFL
Eveon
Femtoprint
FHNW
Flugent
FLUIKA
Fraunhofer ICT-IMM
Fraunhofer IHP
GPB Scientific
HNP-mikrosysteme
HS Coburg
HSG-IMIT
ICN2
Imec
ImmeeDx
IMT Masken Und Teilungen
In2being
Instituto Portugues da Qualida
IOF Fraunhofer
IPHT Leipzig
IVAM
Kirkstall
LionIX
Lumicks
Magnomics
McMaster University
MDX devices
MemSop
MESA+
METAS
MFCS
Micralyne
Microliquid
Micronit
Microxlabs
Nanoscribe
Netzwerks „Lab on a Chip“
Nexterion / Schott
NILT
NIST
Philips
Phoenix
Potomac Laser
Potomac Photonics
Qiagen
Samtec
Scope Fluidics
Siargo-China
Siemens Diagnostics
SLAC National Accelerator Lab
Stiplastic
Stratec
Technical University Dortmund
Technogation
Thinxx
TissUse
TNO
Tronics
TU Berlin
Tyndall National Institute
University College London (UCI)
University of Bath
University of California at San I
University of Florida
University of Texas at El Paso
UPC
Wisenstech
Testing protocols

• Generate Vocabulary, i.e. definitions of properties, components, functions
• Work on the understanding of why and how microfluidic devices fail
• List and describe parameters to be tested. The top three already identified are: burst test -, leakage test - and flow test protocols that measure instantaneous flows.
• Are there existing Norms that we can refer to?
• Utilise existing norms to reduce work load
• Generate protocols for each (not yet specified) parameter
• Certification of measuring protocol required?
• Ensure that suitable test benches / instruments will be developed.
• Work on reference sensors calibrated by external standard institutes that fit better to the microfluidic state of the art.
Vocabulary, establishing a common language

DIN EN ISO 10991
Micro process engineering - Vocabulary (ISO 10991:2009); Trilingual version
EN ISO 10991:2009

DIN EN ISO 10991:2010-03 (D/E/F)

Mikroverfahrenstechnik - Begriffe (ISO 10991:2009); Dreisprachige Fassung EN ISO 10991:2009


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Next steps

- Generate Vocabulary, i.e. definitions of properties, components, functions
- List and describe parameters to be tested
- **Are there existing Norms that we can refer to?**
  - Generate protocols for each (not yet specified) parameter
  - Certification of measuring protocol required?
There are overlaps with other market segments

- Re gas: much is covered by the semi standards for mass flow controllers
- Re fluids: Relevant users are also those involved in drug delivery; see for instance: http://www.drugmetrology.com/images/Publications/2014_10_07_White_paper_on_microflow_and_nanoflow_measurement.pdf
- IEC 60601-2-24 Infusion Pumps and Controllers Testing
- Medical electrical equipment – Part 2-24: the basic safety and essential performance of infusion pumps and controllers

**IEC 60601-2-24 Scope:**
- IEC 60601 2 24 and EN 60601 2 24 testing applies to the basic safety and essential performance of infusion pumps and volumetric infusion controllers, hereafter referred to as medical electronic equipment.
- IEC 60601-2-24 testing applies to administration sets insofar as their characteristics influence the basic safety or essential performance of infusion pumps and volumetric infusion controllers. However EN 60601-2-24 does not specify requirements or tests for other aspects of administration sets

Ref: Henne van Herren
Environmental tests on DE coatings

DIN ISO 10110-7
Optics and photonics - Preparation of drawings for optical elements and systems - Part 7: Surface imperfections (ISO/DIS 10110-7:2016)

ISO 9211-4:2012
Optics and photonics -- Optical coatings - Part 4: Specific test methods

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<thead>
<tr>
<th>No.</th>
<th>Test</th>
<th>Standard</th>
</tr>
</thead>
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<tr>
<td>1</td>
<td>Adhesion</td>
<td>Width of Tape 12.7 mm / quick remove</td>
</tr>
<tr>
<td>2</td>
<td>Moderate abrasion</td>
<td>ISO 9211-01-01 Cheesecloth / 50 strokes / 5 N ± 1 N</td>
</tr>
<tr>
<td>3</td>
<td>Temperature</td>
<td>Customer specification 5 min @ +345°C in air</td>
</tr>
<tr>
<td>4</td>
<td>High T and humidity</td>
<td>Customer specification +90°C / 95% rH / 96h</td>
</tr>
<tr>
<td>5</td>
<td>Thermal cycles</td>
<td>Customer specification -55°C / +120°C / dwell time each temperature 1h / 10 cycles / 10K/min temperature changing rate</td>
</tr>
</tbody>
</table>

Assume an integrated Electrode or Ta₂O₅ waveguide

Graph 2: measured data from thermal cycle test
IEC 62047-1:2016 Semiconductor devices – Micro-electromechanical devices

- Part 1: **Terms and definitions**
- Part 2: Tensile testing method of thin film materials
- Part 3: Thin film standard test piece for tensile testing
- Part 4: **Generic specification for MEMS**
- Part 5: RF MEMS switches
- Part 6: Axial fatigue testing methods of thin film materials
- Part 7: MEMS BAW filter and duplexer for radio frequency control and selection
- Part 8: Strip bending test method for tensile property measurement of thin films
- Part 9: **Wafer to wafer bonding strength measurement for MEMS**
- Part 10: Micro-pillar compression test for MEMS materials
- Part 11: Test method for coefficients of linear thermal expansion of free-standing materials for MEMS
- Part 12: Bending fatigue testing method of thin film materials using resonant vibration of MEMS structures
- Part 13: Bend - and shear - type test methods of measuring adhesive strength for MEMS structures
- Part 14: Forming limit measuring method of metallic film materials
- Part 15: Test method of **bonding strength between PDMS and glass**
- Part 16: Test methods for determining residual stresses of MEMS films - Wafer curvature and cantilever beam deflection methods
- Part 17: Bulge test method for measuring mechanical properties of thin films
- Part 18: Bend testing methods of thin film materials
- Part 19: Electronic compasses
- Part 20: Gyroscopes
- Part 21: Test method for Poisson's ratio of thin film MEMS materials
- Part 22: Electromechanical tensile test method for conductive thin films on flexible substrates
- Part 25: Silicon based MEMS fabrication technology - Measurement method of pull-press and shearing strength of micro bonding area
- Part 26: Description and measurement methods for micro trench and needle structures
- Part 27: **Bond strength test** for glass frit bonded structures using **micro-chevron-tests (MCT)**
- Part 28: Performance testing method of vibration-driven MEMS electret energy harvesting devices
Part 9: Wafer to Wafer bonding strength measurement for MEMS

**IEC 62047-9:2011** describes bonding strength measurement method of wafer to wafer bonding, type of bonding process such as silicon to silicon fusion bonding, silicon to glass anodic bonding, etc., and applicable structure size during MEMS processing/assembly. The applicable wafer thickness is in the range of 10 um to several millimeters.
Part 15: Bonding strength between PDMS and glass

IEC 62047-15:2015 describes test method for bonding strength between polydimethyl siloxane (PDMS) and glass. Silicone-based rubber, PDMS, is used for building of chip-based microfluidic devices fabricated using lithography and replica moulding processes.

The problem of bonding strength is mainly for high pressure applications as in the case of certain peristaltic pump designs where an off chip compressed air supply is used to drive the fluids in micro channels created by a twin layer, one formed by bondage between glass with replica moulded PDMS and another between PDMS and PDMS.

Also, in case of systems having pneumatic microvalves, a relatively high level of bonding particularly between two replica moulded layers of PDMS becomes quite necessary.

Usually there is a leakage and debonding phenomena between interface of bonded areas, which causes unstability and shortage of lifetime for MEMS devices. This standard specifies general procedures on bonding test of PDMS and glass chip.
1 Scope

This standard applies for the definition of possible manufacturing tolerances for plastic moulded parts. It applies exclusively for new designs from the date of issue of this standard.

It involves limit dimensions for size dimensions (two-point dimensions) as indirect tolerancing (general tolerances) and as direct tolerancing (indication of deviation at nominal size dimension).

For tolerancing of form deviation and positional deviation, profile form tolerances act as general tolerances and position tolerances for the direct tolerancing by cylindrical tolerance zone.

Procedural basis of this standard are original mould methods with closed tools such as injection moulding, injection compression moulding, transfer moulding and compression moulding of non-porous moulded parts made from thermoplastics, thermoplastic elastomers and thermosets as well as rotational moulding of thermoplastics.
2 Normative references

The following documents that are cited in this document in whole or part are required for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

DIN EN ISO 286-1, Geometrical product specification (GPS) — ISO code system for tolerances on linear sizes — Part 1: Basis of tolerances, deviations and fits
DIN EN ISO 286-2, Geometrical product specification (GPS) — ISO code system for tolerances on linear sizes — Part 2: Tables of standard tolerance classes and limit deviations for holes and shafts
DIN EN ISO 294-4, Plastics — Injection moulding of test specimens of thermoplastic materials — Part 4: Determination of moulding shrinkage
DIN EN ISO 527 (all parts), Plastics — Determination of tensile properties
DIN EN ISO 1043 (all parts), Plastics — Symbols and abbreviated terms
DIN EN ISO 1101, Geometrical product specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out
DIN EN ISO 5458, Geometrical product specification (GPS) — Geometrical tolerancing — Positional tolerancing
DIN EN ISO 5459, Geometrical product specifications (GPS) — Geometrical tolerancing — Datums and datum systems
DIN EN ISO 8015, Geometrical product specification (GPS) — Fundamentals — Concepts, principles and rules
DIN EN ISO 10135, Geometrical product specifications (GPS) — Drawing indications for moulded parts in technical product documentation (TPD)
DIN EN ISO 14405-1, Geometrical product specifications (GPS) — Dimensional tolerancing — Part 1: Linear Sizes
DIN EN ISO 14405-2, Geometrical product specifications (GPS) — Dimensional tolerancing — Part 2: Dimensions other than linear sizes
DIN EN ISO 18064, Thermoplastic elastomers — Nomenclature and abbreviated terms
DIN ISO 48, Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)
DIN ISO 10579, Technical drawings; dimensioning and tolerancing; non-rigid parts
ISO 2577, Plastics — Thermosetting moulding materials — Determination of shrinkage
D 263® bio of Schott has certified biocompatibility
Cytotoxicity as per DIN EN ISO 10993-5:2009
and
Haemocompatibility as per DIN EN ISO 10993-4:2009

ISO 10993 consists of the following parts, under the general title Biological evaluation of medical devices:
- Part 1: Evaluation and testing within a risk management process
- Part 2: Animal welfare requirements
- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- **Part 4: Selection of tests for interactions with blood**
- **Part 5: Tests for in vitro cytotoxicity**
- Part 6: Tests for local effects after implantation
- Part 7: Ethylene oxide sterilization residuals
- Part 9: Framework for identification and quantification of potential degradation products
- Part 10: Tests for irritation and skin sensitization
- Part 11: Tests for systemic toxicity
- Part 12: Sample preparation and reference materials
- Part 13: Identification and quantification of degradation products from polymeric medical devices
- Part 14: Identification and quantification of degradation products from ceramics
- Part 15: Identification and quantification of degradation products from metals and alloys
- Part 16: Toxicokinetic study design for degradation products and leachables
- Part 17: Establishment of allowable limits for leachable substances
- Part 18: Chemical characterization of materials
Next steps

• Generate Vocabulary, i.e. definitions of properties, components, functions
• List and describe parameters to be tested
• Are there existing Norms that we can refer to?
• Utilise existing norms to reduce work load
• Generate protocols for each (not yet specified) parameter
• Certification of measuring protocol required?
Characterization platform for flow related issues and leakage
Microfluidic Probe Station

**Microfluidic Probe Station Flow control unit**
- programmable pressure driven flows
- feedback regulation by integrated flow sensors
- optical monitoring via inverted microscope

**Metrology of fluid flow**
- measure channel flow profiles
- compare to simulations

**Particle image velocimetry (PIV)**
- fluorescent μ-particles
- optical monitoring via inverted microscope

**Test chip**

**Requirement for acting as a development partner for MF solutions:** Chip design validation & optimization
Microfluidic Probe Station

Microfluidic Probe Station Flow control unit
• programmable pressure driven flows
• feedback regulation by integrated flow sensors
• optical monitoring via inverted microscope

Metrology of fluid flow
• fluidic functionality tests
  - evaluation of chip performance
    (e.g. mixing, sorting, etc.)

requirement for acting as a development partner for MF solutions: Chip design validation & optimization
Internal Quality Control of MF Chips

Mechanical tests of Microfluidic Chips: Bonding

- non-destructive leakage test (DIN EN 1779) for chip defect detection
  - filling of chip with gas at operating pressure
  - monitor pressure loss for leakage detection
- burst pressure tests for bonding strength test
  - increase pressure until
  - chip breakdown occurs

• Quality Control for production of MF chips
• Future plan: include electrical microprober for QC of chips with integrated electrodes
Pressure test methods and set-up

Non-destructive testing sealing test (DIN EN 1779)
- Werker-Water bath-test resp. Bubble bath
- Sealing test with test-gas
- **Air driven systems**
  - Over-pressure method (D1 DIN EN 1779)
    - Fill sample with nominal pressure
    - Wait for equilibrium
    - Measure pressure drop (→Leakage)
  - Differential pressure systems (D3 DIN EN 1779)
    - Fill sample and reference with nominal pressure
    - Measure pressure drop between sample and reference → Higher sensitivity

- Relatively cheap purchasing and maintaining costs
- Quick and precise with small volumes (small leaks have a large effect)
- 1. choice for „professionall“ QC
Generate protocols for each parameter

Application classes, P&T
- How do we define an application class?
- Accelerated life time?
- steady state or cycling?
- Pressure- and thermo-cycling separately/combined?
- How many cycles are sufficient?

Graph 2: measured data from thermal cycle test
Next steps in the working groups

- Generate Vocabulary, i.e. definitions of properties, components, functions
- List and describe parameters to be tested
- Identify existing Norms and utilise existing norms to reduce work load
- Generate protocols for each (not yet specified) parameter
- Decide on Certification of measuring protocol(s)

3rd workshop at CEA-LETI, Grenoble [FR] March 6th & 7th 2018

Focus on the technical WG working on the preparation of standards

The 2 « transversal » themes should be treated by the MFA board or in plenary (vocabulary + marketing data and lobbying)

- Modularity
- Flow control
- Testing
- Interface
Thank you for your attention!