IDEA

International Dialogue for the Evaluation of Allergens

IDEA: The surveillance project

Prof Thomas Rustemeyer

Member, IDEA Supervisory Group

Annual Review 2019 ● European Parliament ● 25 February 2019

Feasibility of a study to assess effectiveness of QRA2

Three IDEA Working Group meetings were held on the topic of feasibility of a study to assess the effectiveness of QRA

- 6 April 2016
- 15 February 2017
- 7 December 2017

All related documents available on IDEA website

Feasibility of a study to assess effectiveness of QRA2 – Key conclusions

- A surveillance system alone may not verify whether the Quantitative Risk Assessment (QRA) is effective due to confounding factors.
- Complementary work would be necessary.
- Despite the confounding factors, diagnostic patch testing of dermatology clinic patients (surveillance) was seen as a critical pillar in the long term evaluation of the QRA.
- Include new materials (beyond of what is already part of routine patch testing).
- Following trends for specific materials may direct additional work.
- Determine adequate patch testing concentration for new ingredients in a range finding study and develop respective protocol.
- Arrange for data reporting and management via an existing system (EECDRG and or ESSCA) and assess most suitable approach in pilot study.

EECDRG = European Environmental and Contact Dermatitis Research Group / ESSCA = European Surveillance System on Contact Allergens

Surveillance project: Objectives

- The **surveillance system** will be an industry-stakeholder partnership in data generation, analysis and publication
- It will serve as an early-alert-system by collecting information on development of contact allergy rates in the clinics
- It will provide learnings on exposure conditions of the patients to:
  - gain greater insight as to whether the risk assessment and management measures in place are adequate and broad enough in scope
  - allow corrective measures to be identified and taken if needed
- Study also includes quality control element to improve data quality – e.g. training session, site visits and use of a new syringe dosing system for all materials (allowing more precise dosing)

Surveillance project – new materials 1

Based on criteria developed in the IDEA WG:

- *Preferably non natural ingredient*
- *Consideration of proposed extended EU list for consumer information*
- *Industry risk management driven by sensitization endpoint in addition to existing fragrance markers*

in addition to fragrance markers and individual fragrance allergens more or less routinely tested, 7 fragrance materials, so far not in the scope of systematic screening, were selected.

Surveillance project – new materials 2

Name of material	CAS number of material	Volume of Use	Listed in the 2012 SCCS tables 13-1, 13-2 or 13-3, preferably on list 13-1	Listed in the 2013 Commission regulatory proposal	NESIL (µg/cm²)	Synthetic or natural	Status IFRA Standards	Used as flavour
Furaneol [4-Hydroxy-2,5-dimethyl-3(2H)-furanone]	3658-77-3	Moderate/low VoU (5000 kg/y 2015). Use 1984 to present.	NO	NO	590	Synthetic material (but presence in natural extracts)	Will receive an IFRA Standard	YES
trans-2-Hexenal	6728-26-3	Moderate VoU (8000 kg/y 2015). Use 1984 to present.	YES	NO	24	Synthetic material (presence in natural extracts limited)	Has an IFRA Standard	YES
4,8-Dimethyl-4,9-decadienal	71077-31-1	Moderate VoU (8000 kg/y 2015). Use 1984 to present.	NO	NO	550	Synthetic material (presence in natural extracts limited)	Will receive an IFRA Standard	NO
Longifolene	475-20-7	High VoU (268000 kg/y 2015). Use 1984 to present.	YES	NO	3500	Synthetic material (abundant presence in natural extracts)	Will receive an IFRA Standard	YES
Benzaldehyde	100-52-7	Moderate VoU (2000 kg/y 2015). Use 1984 to present.	YES	YES	590	Synthetic material (but presence in natural extracts)	Has an IFRA Standard	YES
Oak moss (with atranol and chloroatranol content at trace levels)*	90028-68-5; 9000-50-4; 68917-10-2	High VoU (44000 kg/y 2015). Use 1984 to present.	YES	YES	700	Natural material	Has an IFRA Standard	NO

*** Additional information: this material is not tested in the Standard series but is the quality now used in products compliant with IFRA Standards and the EU legislation, it would be interesting to collect clinical data ; recommended to also include Tree moss**

Surveillance Project: current status

1. Protocol with Case Report Form (CRF) developed and agreed
2. Dose range-finding study for adequate patch test concentration will be run in several clinics
3. This will also serve as pilot study to iron out system bugs and to provide information on most suitable data reporting system
4. Reached out to clinics that might participate in the pilot study and the partner to run data management
5. Positive feedback, now in process of doing site visits, addressing individual questions developing contracts and providing support on site-specific informed consent forms

Surveillance Project: conclusion

1. Important step for future consumer protection regarding 7 fragrance ingredients not yet part of routine patch testing
2. For the pilot, sufficient partners are in place (clinics, data reporting and patch test manufacturer) and the protocol is completed and agreed.
3. This pilot study will serve as basis for the envisaged European multicenter study “Extended Fragrance Ingredient Surveillance Study (EFISS)”. Further discussions with the SCCS and other stakeholders would be welcome.