Science in Brief newsletter EAACI

The Future of Specific Immunotherapy in Europe

Allergens are MEDICINAL PRODUCTS

Medicinal products REQUIRE MARKETING AUTHORISATION

Dr Carmen Vidal on behalf of the Spanish Committee of Allergen Immunotherapy

What Spanish allergists think about the AIT REGULATORY PROCEDURE

According to the Spanish Agency of Drugs there will be 3 quality LEVELS:

1. Final Product
2. Bulk
3. NPP (Named Patient Products)

Methods

- An e-survey was launched in order to collect the opinion from spanish allergists in 4 main aspects:
  - Final Product
  - Mixtures
  - Evidence
  - Miscellaneous
- 74 AIT experts were invited, 56 (74%) fulfilled the questionnaire

Dejo el logo en todas, yo creo que merece ser dejado porque son datos SEAIC, pero lo quito si os parece fuera de lugar

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- **State what is the relevance** (according to the prevalence of allergy) **of each allergen for its registry as "final product" for AIT:**
  - Scale:
    - High
    - Moderate
    - Mild
    - None

Percentage of doctors considering allergens of High or High+moderate relevance:

ALLERGEN	HIGH relevance	HIGH + MODERATE
Dermatophagoides pteronyssinus	89.3%	94.7%
Phleum pratense	85.7%	96.4%
Grass mixture	82.1%	98.2%
Olea europea	83.9%	92.8%
Alternaria alternata	80.4%	94.7%
Cat dander	72.3%	90.2%
Dog dander	60.7%	87.5%
Dermatophagoides farinae	55.4%	87.5%
Parietaria spp	51.8%	76.8%
Horse dander		71.4%
Cupressus arizonica		96.4%
Platanus acerifolia		83.9%
Salsola kali		76.8%
Lepidoglyphus destructor		60.7%

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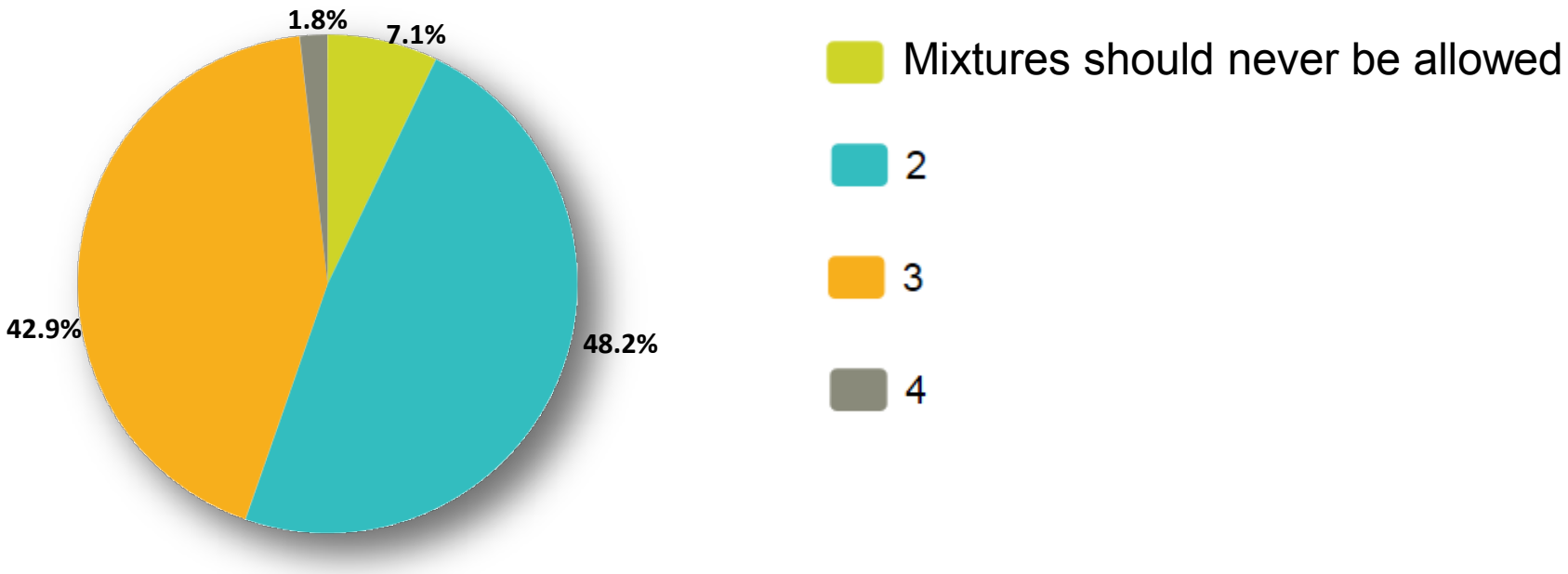
- What is the **maximum** number of different **allergens** that should be **allowed to mix** in the same vaccine?



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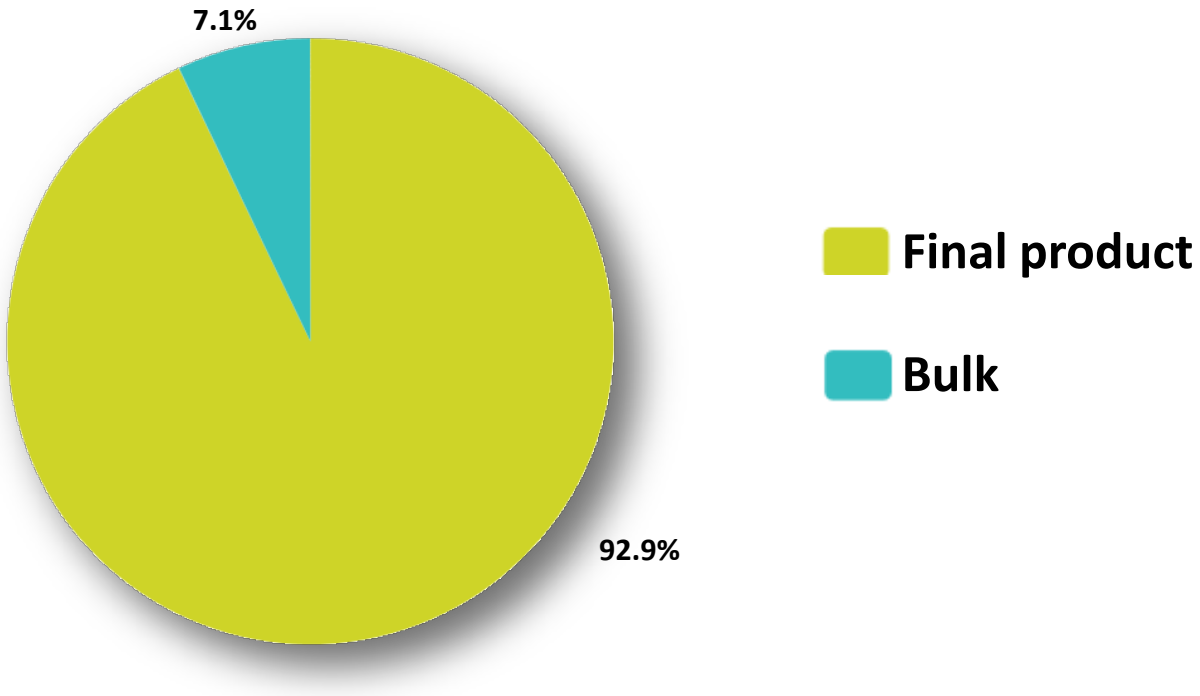
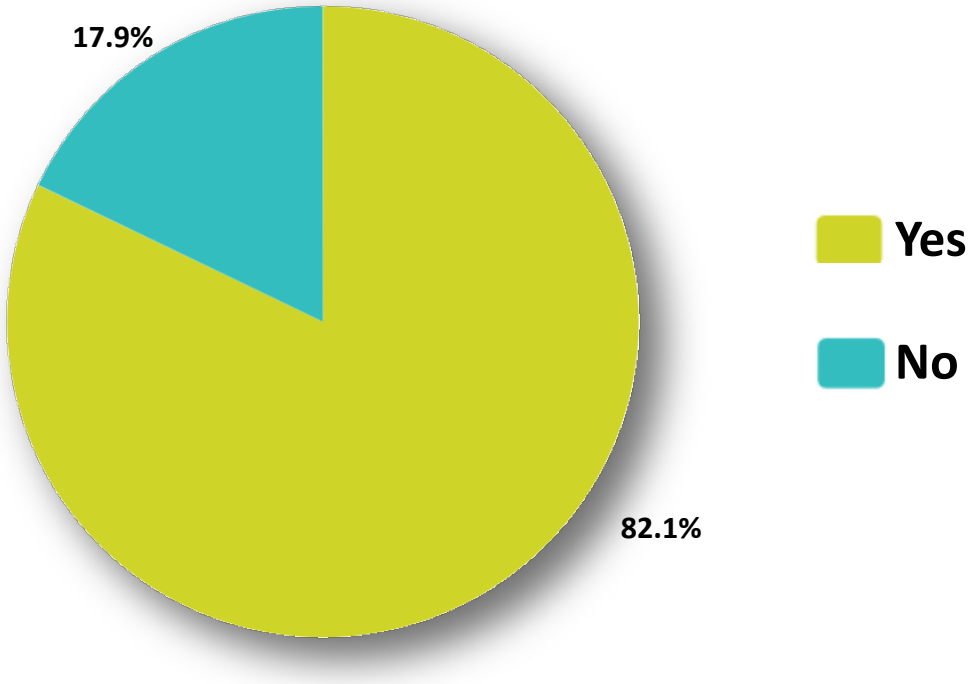
- What would **you prefer** to use in your practice: **bulk or final product** AIT?



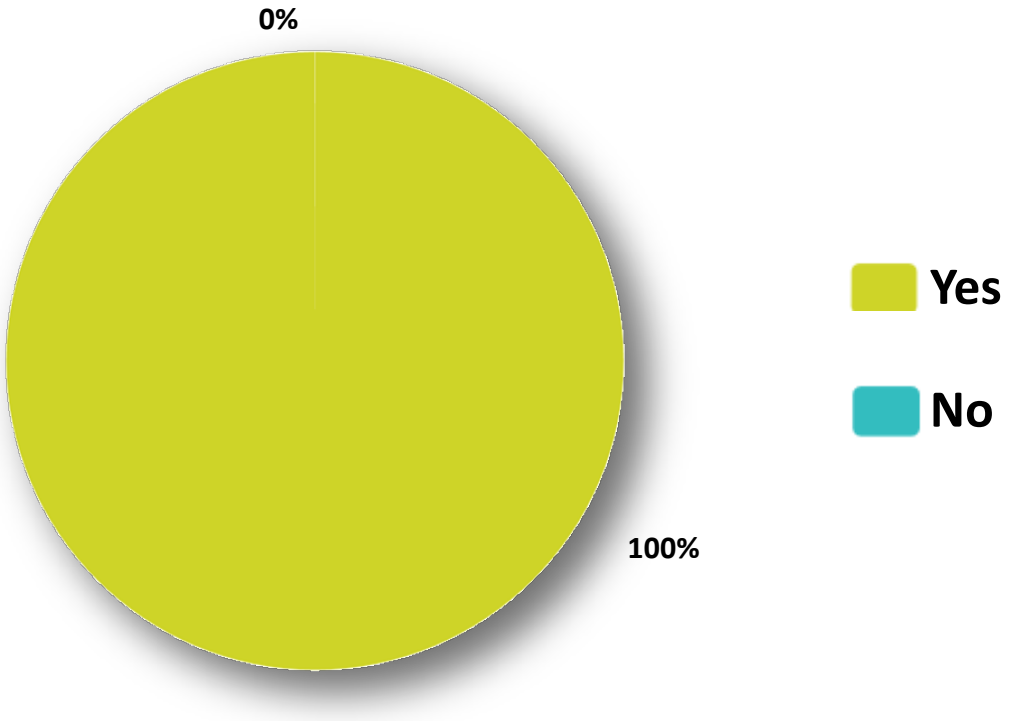
Miscellaneous

- Is it **better** to register **mixtures** as **Final Product than** creating individual **mixtures** from **bulk** products?:



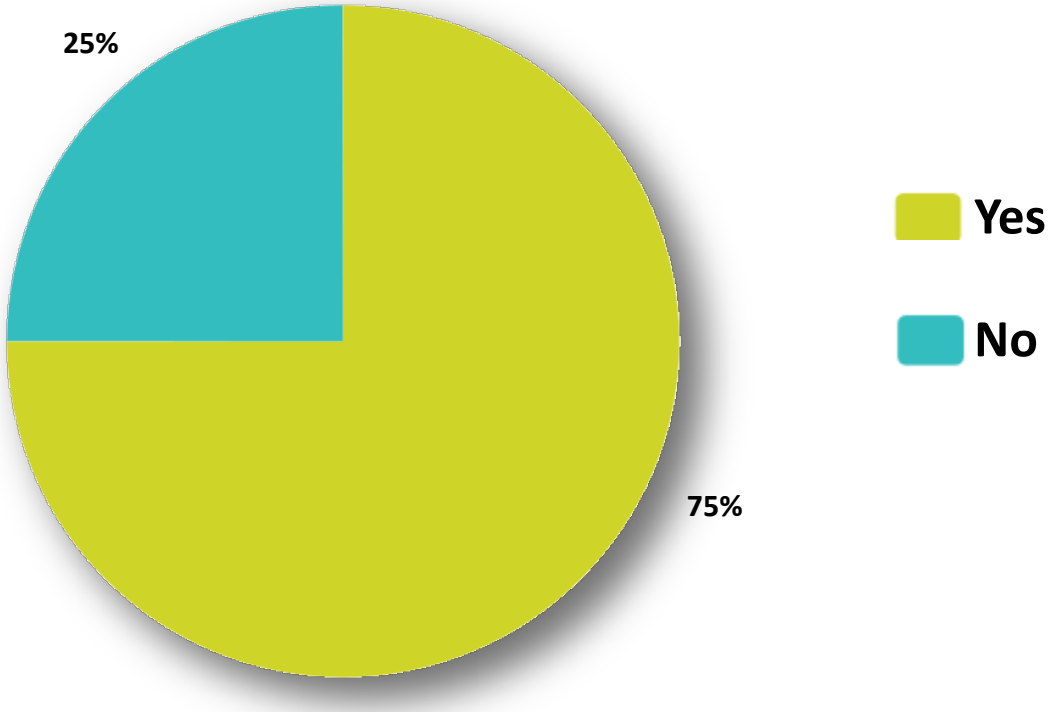
Miscellaneous

- **Efficacy** of each specific allergen used **in AIT** must **ALWAYS** be **evidenced:**



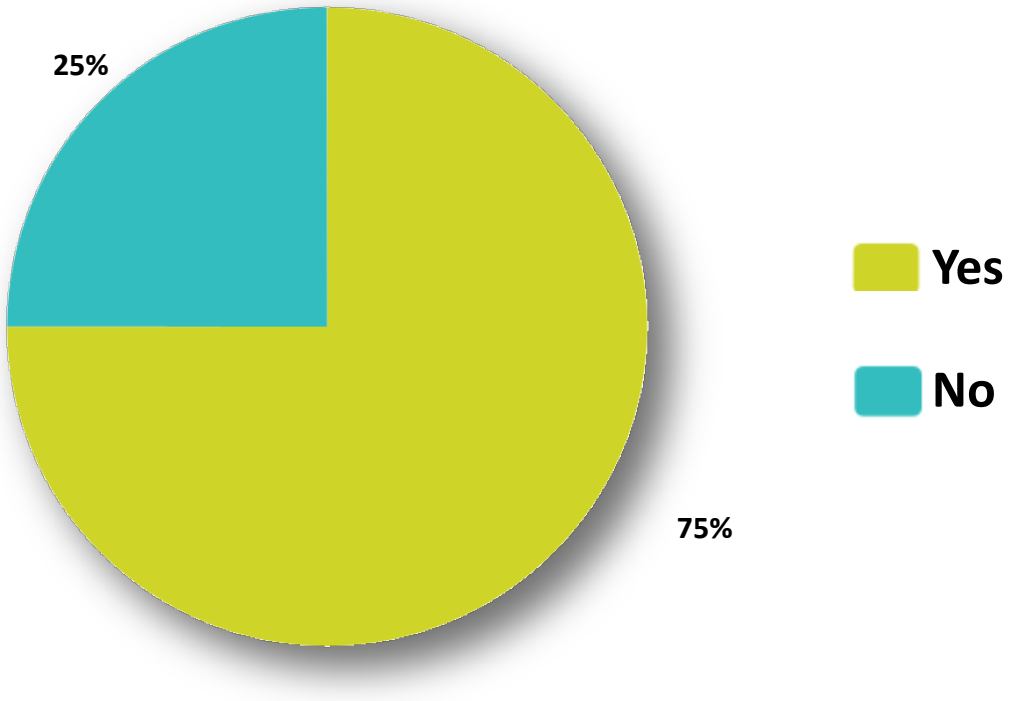
Miscellaneous

- The **regulatory agencies** should **limit** the **NUMBER** of **allergens** to be included **in a mixture**



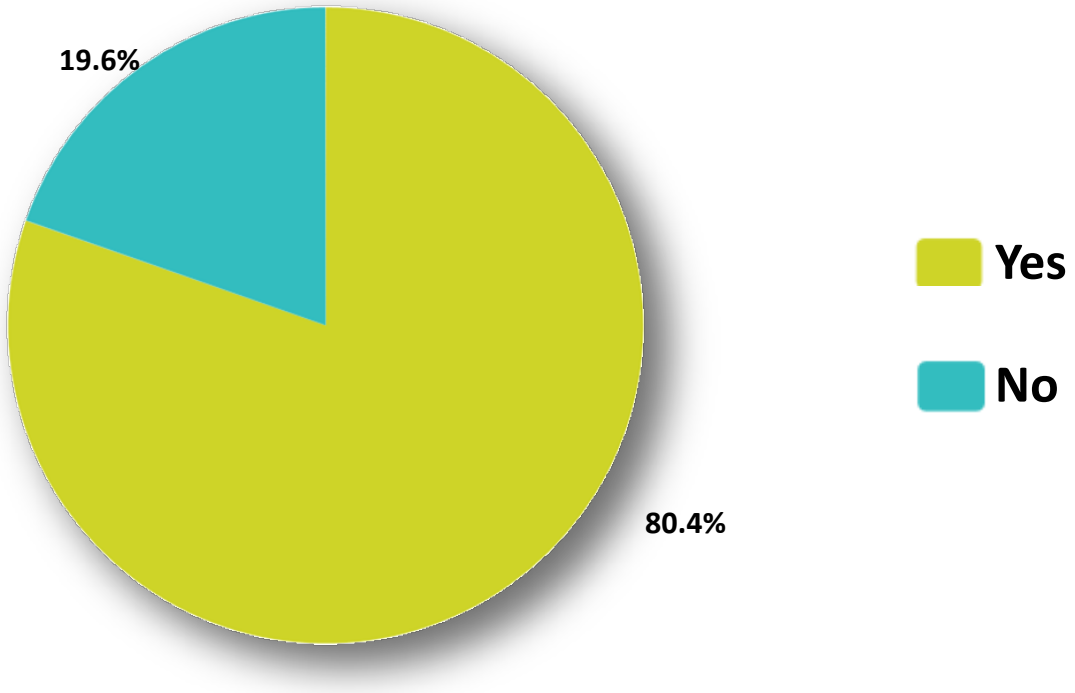
Miscellaneous

- The **regulatory agencies** should **limit** the **TYPE** of **allergens** to be included **in a mixture**



Miscellaneous

- Do you consider that **“Named patient products”** should be **allowed?**



Miscellaneous

- I think it´s good **“named patient products”** are allowed **ONLY for low prevalence allergens** (ie: flour)