

## ABSTRACT

Published specifications for the identity and purity of food ingredients are a critical component of the U.S.'s food safety net. Since the initial publications of specifications for food ingredients by the *Food Chemicals Codex* and the JECFA more than forty years ago, a significant number of new substances have entered the global food supply. Additionally, new developments in manufacturing technologies and food safety chemistry and toxicology have required the continued elaboration of the specifications necessary to establish the quality, and thus the safety, of ingredients. The objective of our study was to estimate the number of food ingredients currently used in the U.S. that lack published specifications, and to assess the challenges in modernizing existing specifications. A preliminary analysis found that more than 40% of the non-flavor

food ingredients used in the U.S. and more than 20% of the FEMA GRAS'd flavoring substances used in the US do not have published standards. Of the specifications available for flavoring substances, many lack detailed analytical conditions to establish purity. Moreover, recent contamination issues, such as melamine in wheat gluten, have highlighted the need to improve the specificity of existing analytical procedures. Also garnering much attention are developments in nanotechnology and biotechnology which can affect food ingredients specifications. Results of our study suggest opportunity to develop new specifications for those ingredients lacking them, to improve the analytical specificity of existing test procedures, and to modernize specifications to address developments in nanotechnology and biotechnology.

## INTRODUCTION

- The *Food Chemicals Codex (FCC)* and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) have served to protect the U.S. food supply for more than forty years by developing public standards for food ingredients including specifications for the identity and purity and supporting test procedures
- Since the initial publications of FCC and JECFA the food ingredient industry has evolved in the development of new food ingredients and methods of manufacturer, and advances in food safety and analytical chemistry.

## OBJECTIVES

- To determine the number of food ingredients used in the U.S. which lack FCC/JECFA published specifications
- To assess potential opportunities to modernize existing FCC/JECFA test procedures
- To assess new areas of food technology which may impact the development of future food ingredient specifications

## METHODS

- List of non-flavoring agent food ingredients used in U.S. compiled using FDA's EAFUS list [1] with the following modifications
  - » Added all food ingredients listed on FDA's GRAS Notices webpage [2]
  - » Removed all DOCTYPE = "BAN" food ingredients
  - » Removed all flavoring agents listed in CFR 172; 182; 184
  - » Removed all FEMA GRAS'd flavoring agents through the 23rd FEMA GRAS list [3]
- » Removed all food ingredients regulated only as indirect food additives in CFR 181.3 - 181.3299; 182.7 - 183; 175-179; 186
- List of all flavoring agent food ingredients used in U.S.A. assembled using FEMA GRAS'd flavoring agents through the 23rd FEMA GRAS list [3]
- List of published specifications for food ingredients assembled using the Sixth Edition of the Food Chemicals Codex [4] and JECFA's Compendium of Food Additive and Flavouring Agents Specifications [5]

## RESULTS

### 1132 Total Non-Flavoring Agent Food Ingredients Used in the U.S.

- 543 (48%) Have Specifications in Either FCC or JECFA
- 589 (52%) Lack Specifications in Both FCC and JECFA

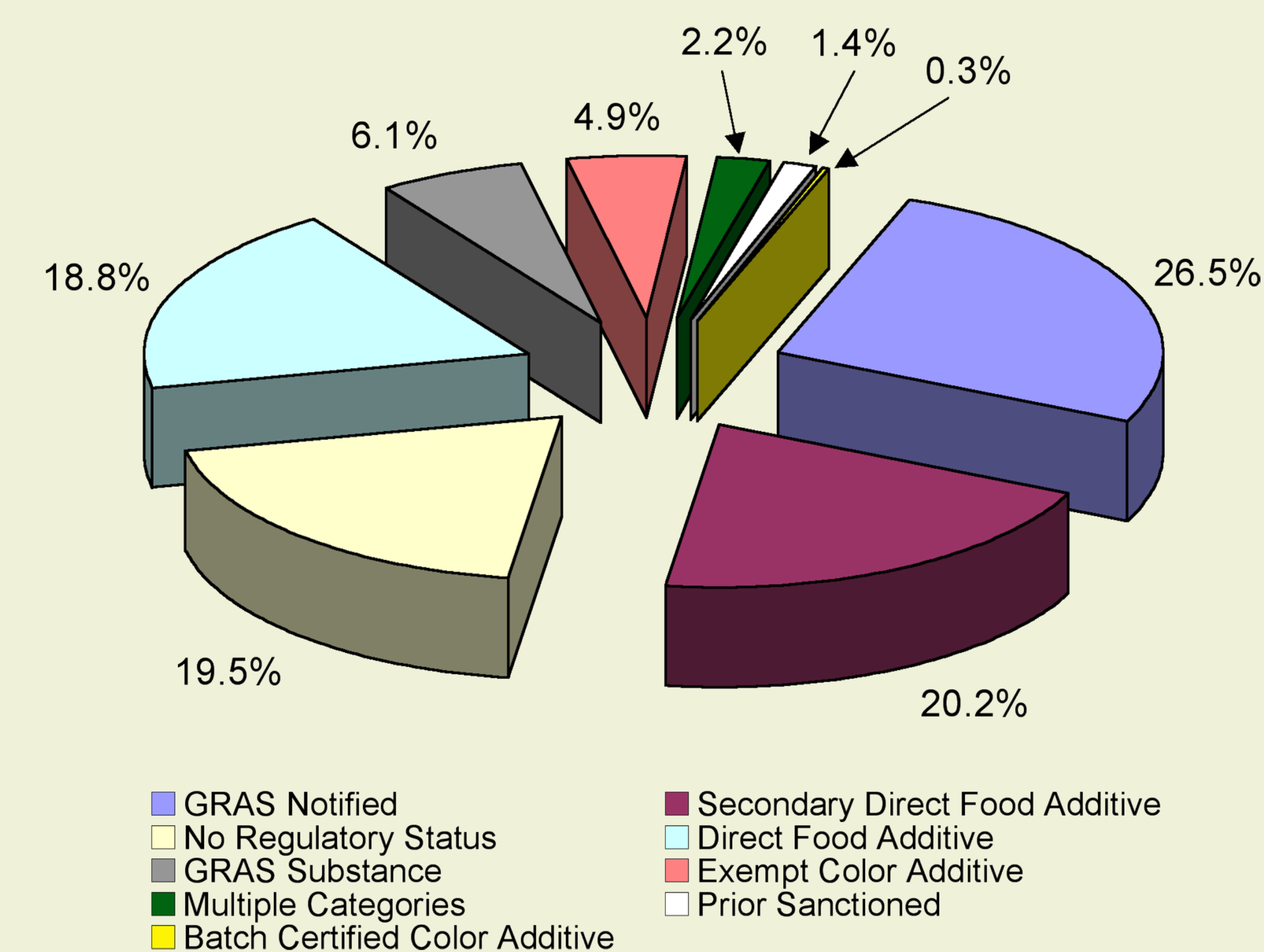


Figure 1. US Regulatory Categories for Non-Flavoring Agent Food Ingredients Lacking Published Specifications

### Opportunities to Modernize Existing FCC and JECFA Analytical Test Procedures

- Flavor chemicals: Addition of detailed GC analysis conditions for purity (Assay) test procedures and the use of reference standards; Use of GC/MS
- Non-flavors: Improving the specificity of purity (Assay) test procedures, especially for food ingredients at risk for economic adulteration such as wheat gluten

### 2429 Total Flavoring Agent Food Ingredients Used in the U.S.

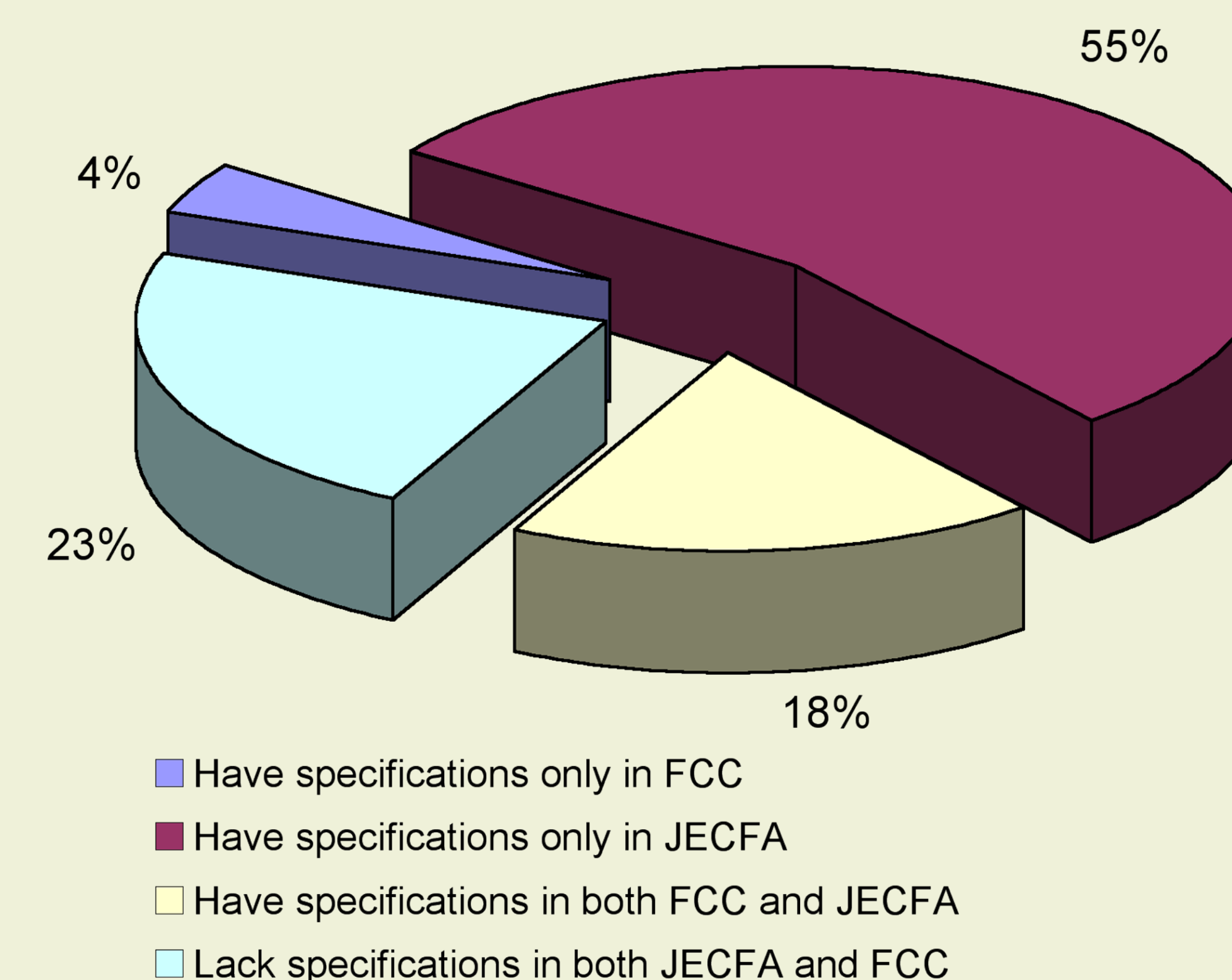


Figure 2. Availability of Published Specifications for Flavoring Agents Used in the USA

- Emerging Food Ingredient Technologies
- Nanotechnology: Several nanoscale food/dietary supplement ingredients are in development or already in the market [6,7]
- Biotechnology: Numerous GM-food ingredients and biotechnological methods of manufacture already in use [8]

## CONCLUSIONS

- Opportunities exist to strengthen the U.S.'s food safety net through published food ingredient specifications and test procedures including:
  - » Developing specifications for the 52% of the non-flavoring and 23% of the flavoring agent food ingredients used in the U.S. which lack them
  - » Modernizing existing test procedures in FCC and JECFA
  - » Developing compendial strategies to address emerging food technologies

## REFERENCES

- [1] <http://www.cfsan.fda.gov/~dms/eafus.html> (accessed January 4, 2008)
- [2] <http://www.cfsan.fda.gov/~rdb/opa-gras.html> (accessed May 15, 2008)
- [3] Waddel, W.J. et al. 2007. GRAS Flavoring Substances 23. *Food Tech* 61(8): 22-61.
- [4] The United States Pharmacopeial Convention, Inc. 2008. *The Food Chemicals Codex*. 6th Ed. Baltimore: United Book Press.
- [5] JECFA. *Compendium of Food Additive and Flavouring Agents Specifications*. [http://www.fao.org/ag/agn/agns/jecfa\\_archive\\_en.asp](http://www.fao.org/ag/agn/agns/jecfa_archive_en.asp) (accessed January 4, 2008)
- [6] Chaudhry, Q., et al. 2008. Applications and implications of nanotechnology for the food sector. *Food Addit. Contam.* 25(3): 241-258
- [7] <http://www.nanotechproject.org/> (accessed May 15 2008)
- [8] <http://www.fao.org/docrep/009/a0744e/a0744e00.htm>