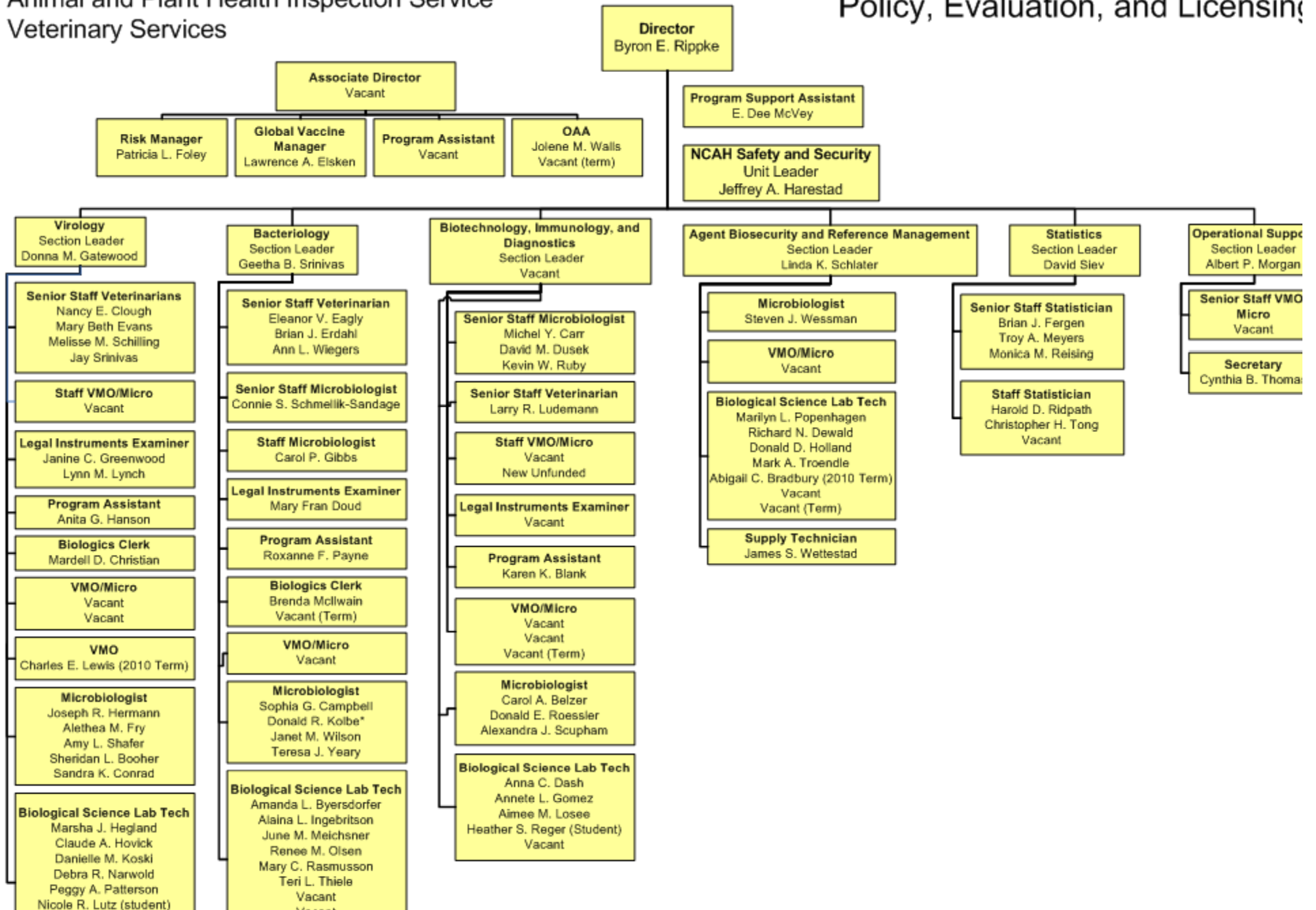


PEL UPDATE

USAHA 2010

United States Department of Agriculture
 Animal and Plant Health Inspection Service
 Veterinary Services

Center for Veterinary Biologics
 Policy, Evaluation, and Licensing



PEL 2010 Priority Activities

- CVB Operational Priorities
 - Mycoplasma PCR test development
 - Extraneous Agent Microarray development
 - LSRTIS data population and implementation
 - BID Section testing backlog
 - Firm merger activities
- Application Review
- Management & Culture Review activities
- Program Documentation & Quality Assurance
- pH1N1

2010 Program Documents

- CVB Notices Published – 10
- VS Memorandums Published – 2
- Documents Posted to the CVB Website for Comment – 11
- Federal Register Publications – 1 Notices

FY 2010

Establishments and Permittees

Issued

1 Establishment Licenses

8 Permittee

Terminated

10 Establishment License

4 Permittee

Total

77 Licensees

22 Permittees

FY 2010 Products

Issued

57 Product Licenses

These include: 1 Unique Products

Terminated

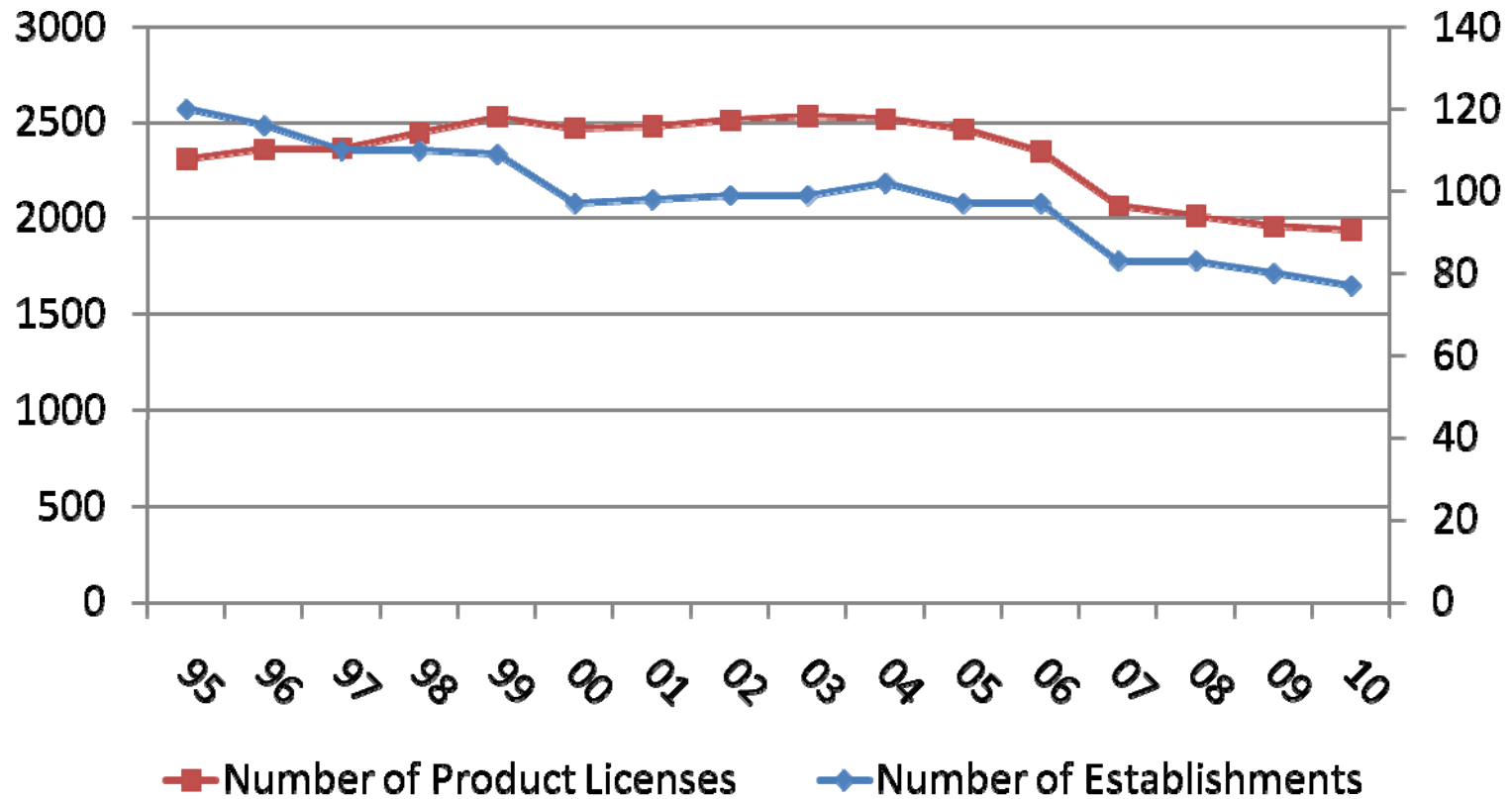
106 Product Licenses

Total

1,942 Active Product Licenses

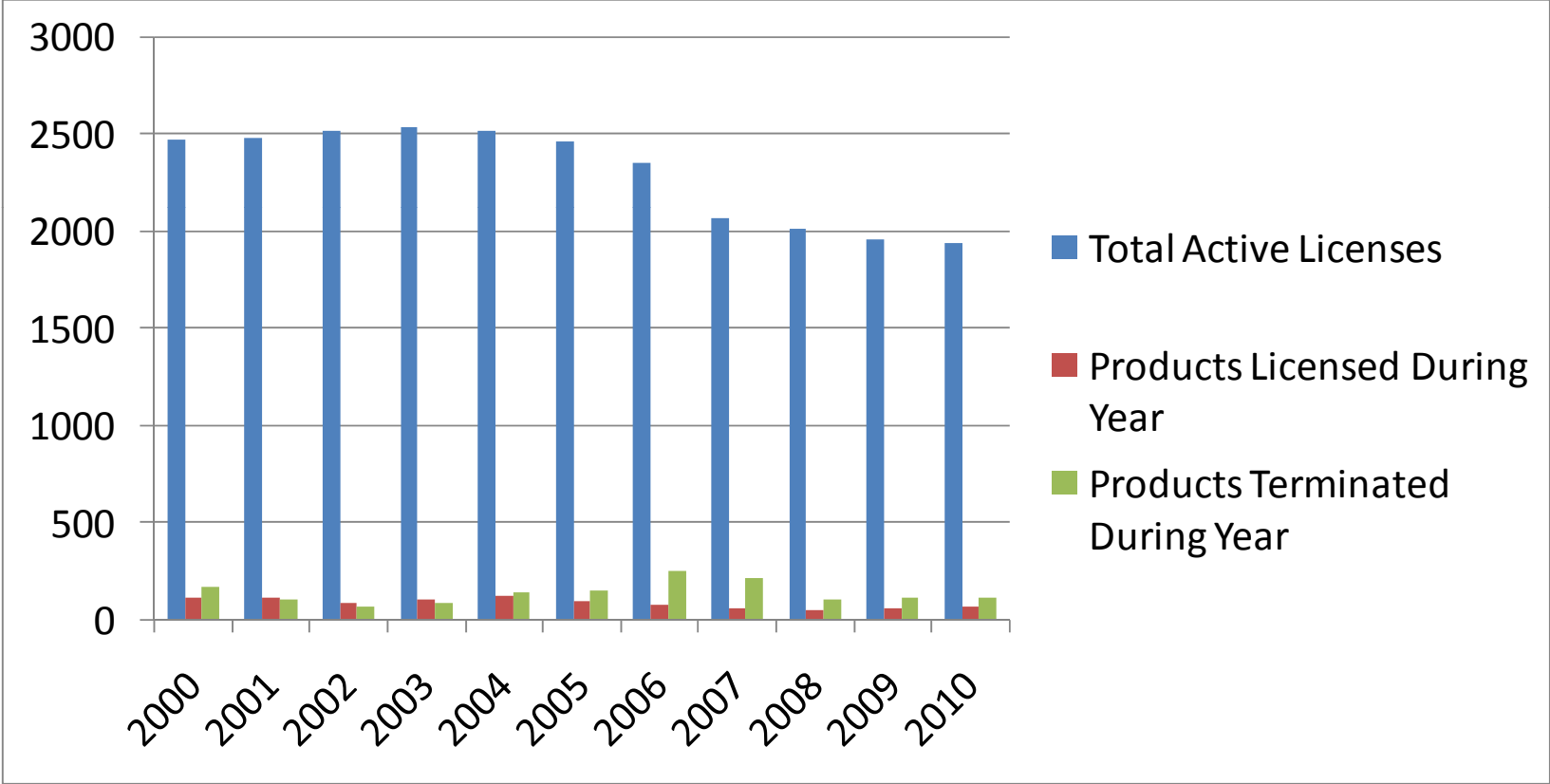
Licensed Establishments vs. Products

Products by Year Establishments



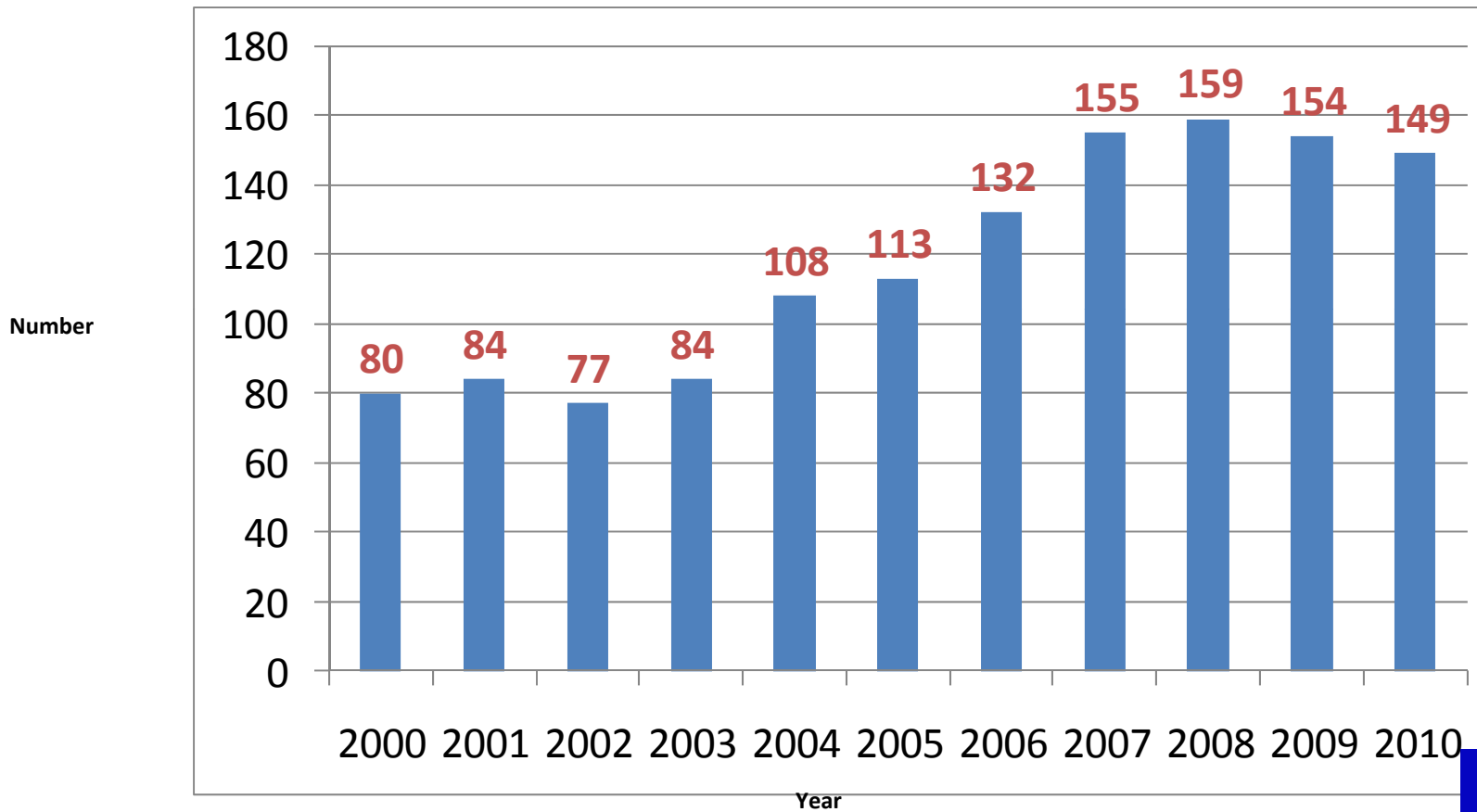
FY2010 Value as of 09/30/10

Product License Activity by Year

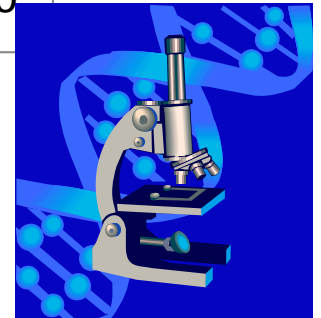


FY2010 Licensed and Terminated Values from 10/01/2009 to 09/30/2010

Active Biotech Product Licenses

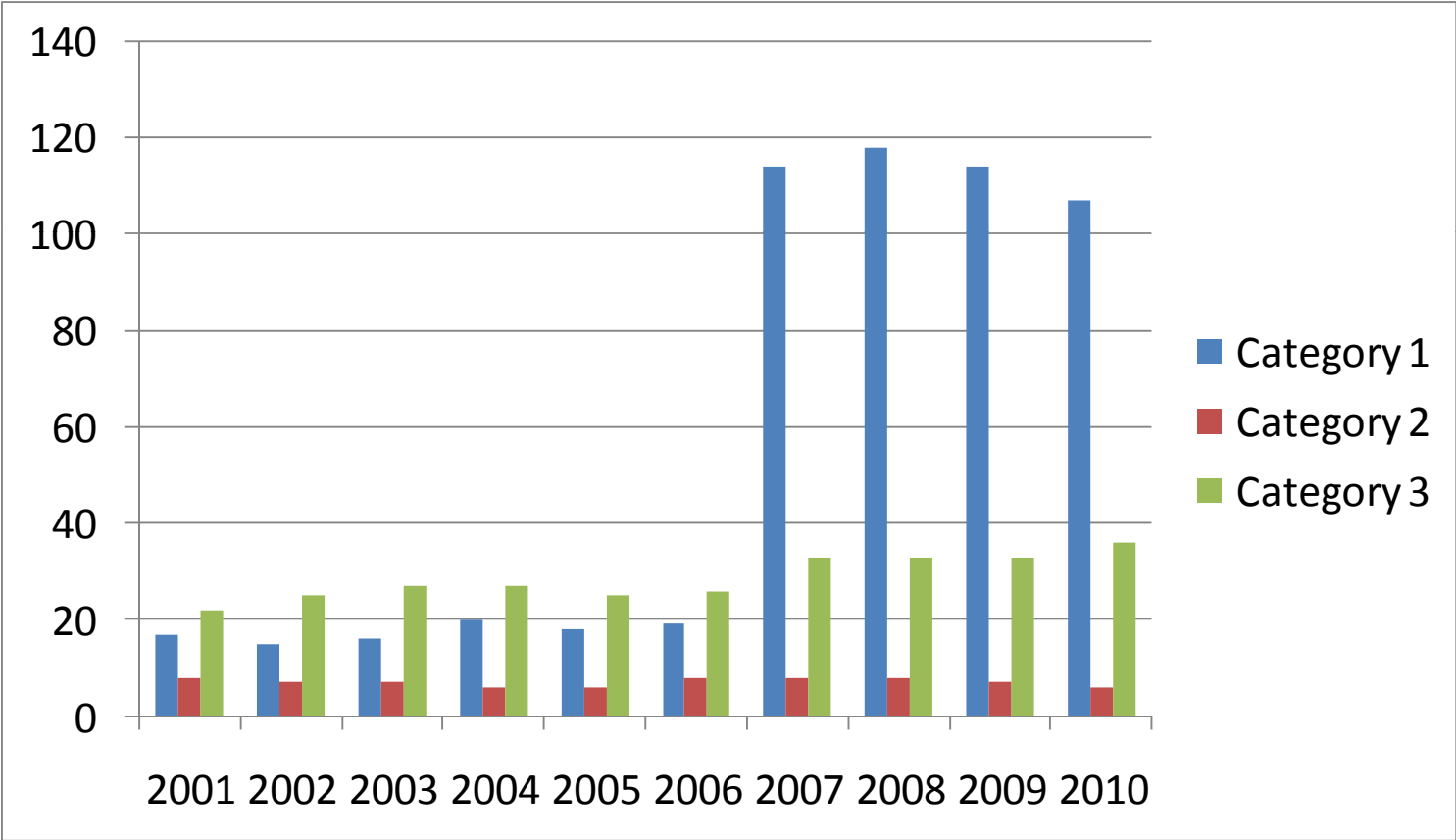


FY2010 Value as of 09/30/10



Biotech Products by Category by Year

Number



Note: Figures for 2001-2006 do not include Diagnostics.

FY2010 Values as of 09/30/10

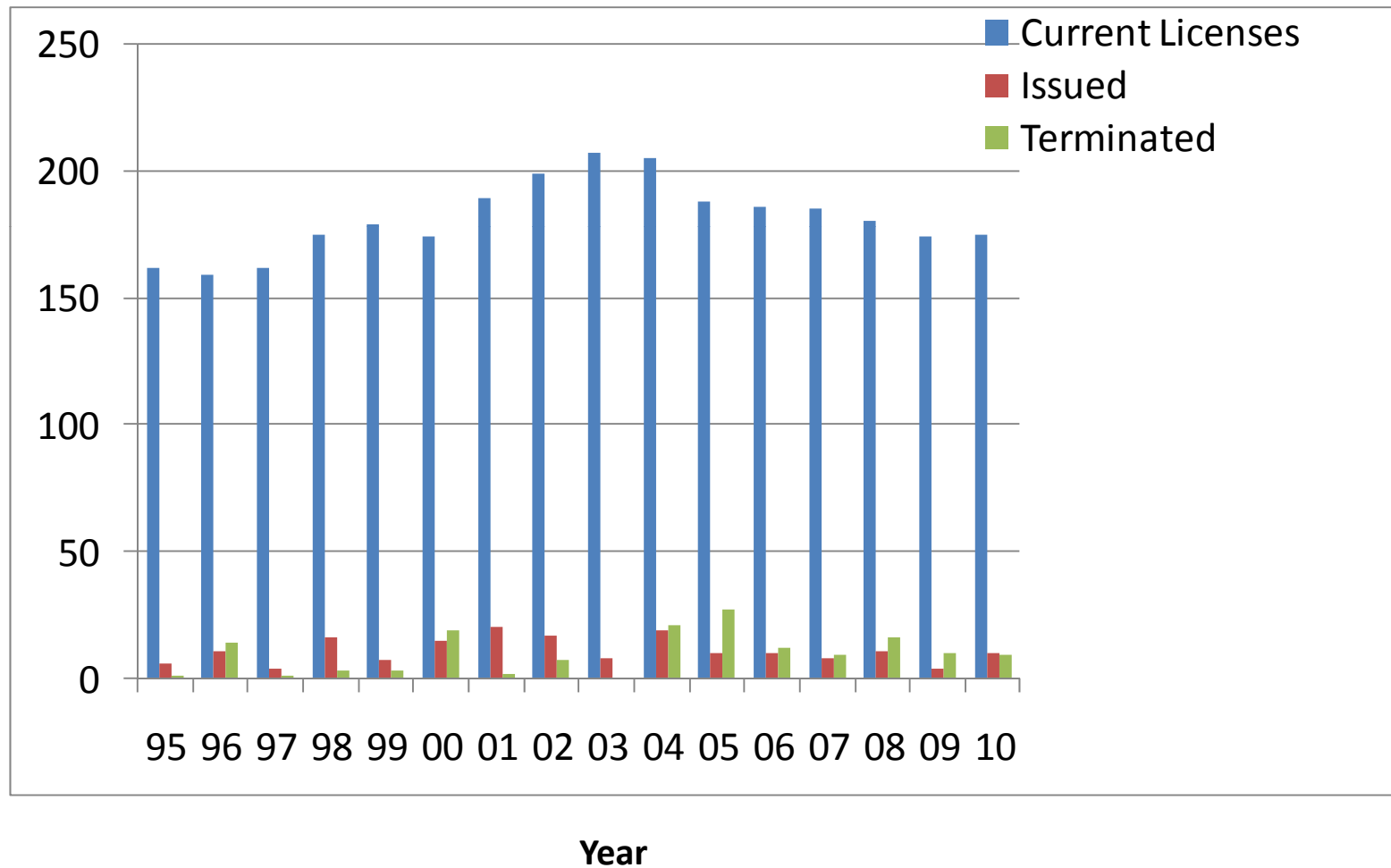
Biotech Products – FY2010

All Categories (as of 09/30/10)

Category I		Category II	
I-A-1 Non-replicating recombinant antigen(s)-vaccine	12	II Live Gene Deleted	6
I-A-2 Non-replicating recombinant antigen(s)-kits	14	Category III	
I-B-1 Monoclonal antibody-therapeutic/prophylactic use	1	III-A Live Vectored	36
I-B-2 Monoclonal antibody-used in diagnostic tests	67	III-B-1 Transgenic plant-based vaccine	0
I-C-1 Synthetic peptide-therapeutic/prophylactic use	2		
I-C-2 Synthetic peptide/oligonucleotide-in diagnostic	7		
I-D-1 Nucleic Acid-Mediated (not Synthetic)-vaccine	2		
I-D-2 Nucleic Acid-Mediated (not Synthetic)-diagnostic	2		

Number of Diagnostic Product Licenses

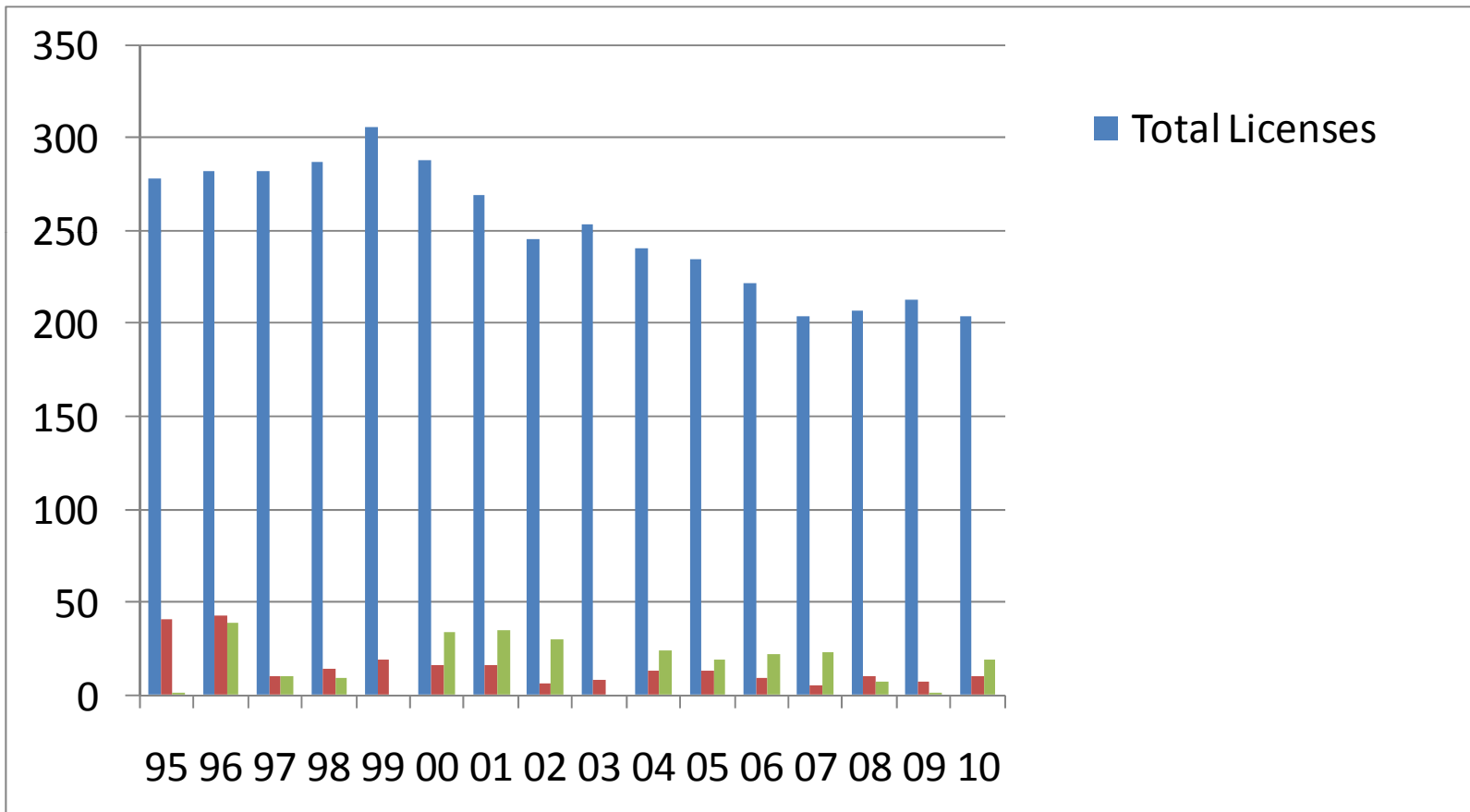
Number



FY2010 Values from 10/01/09 – 09/30/10

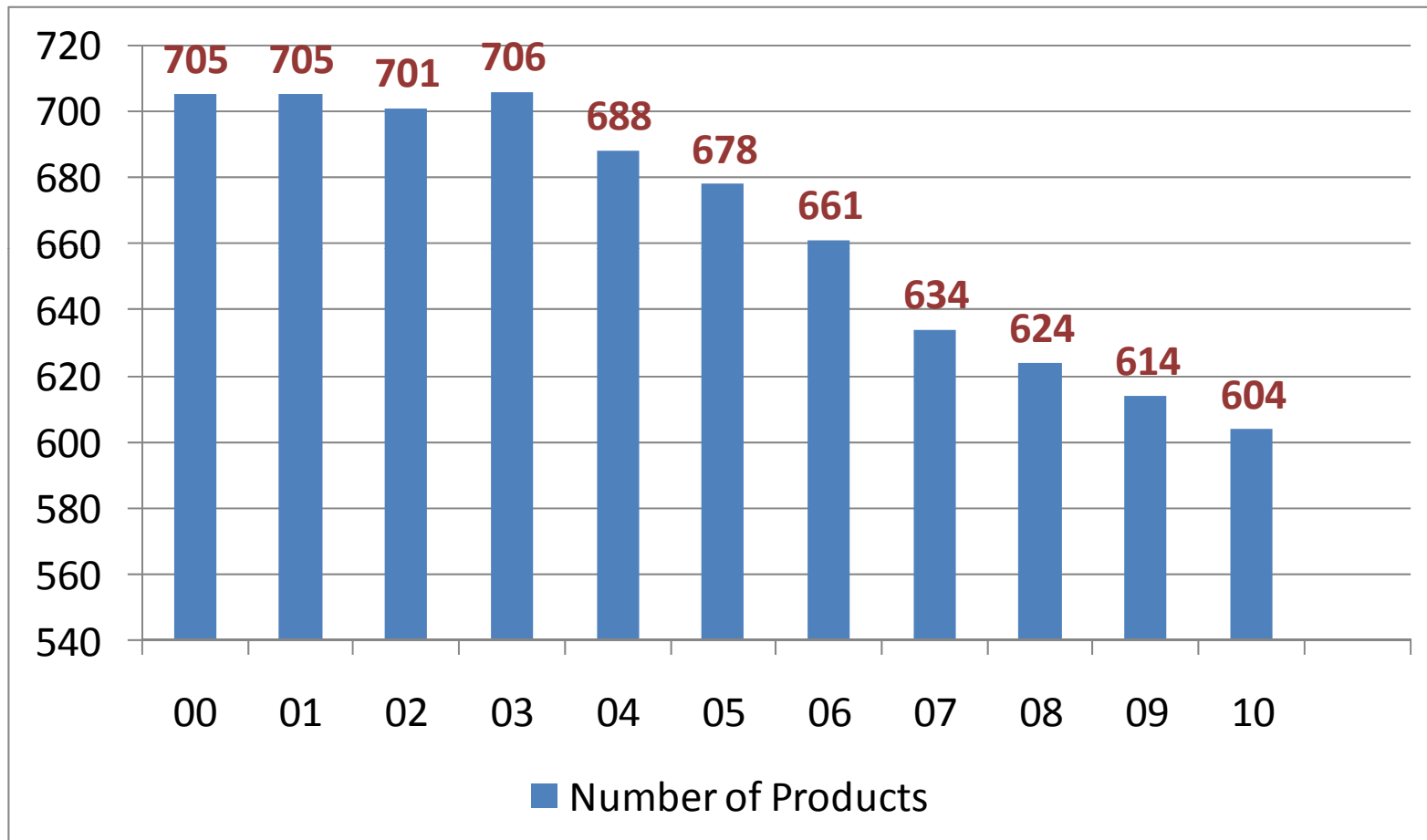
For Further Manufacture Products Licensed by Year

Number



Licensed and Terminated Values from 10/01/09 through 09/30/10

Active Unique Products by Year



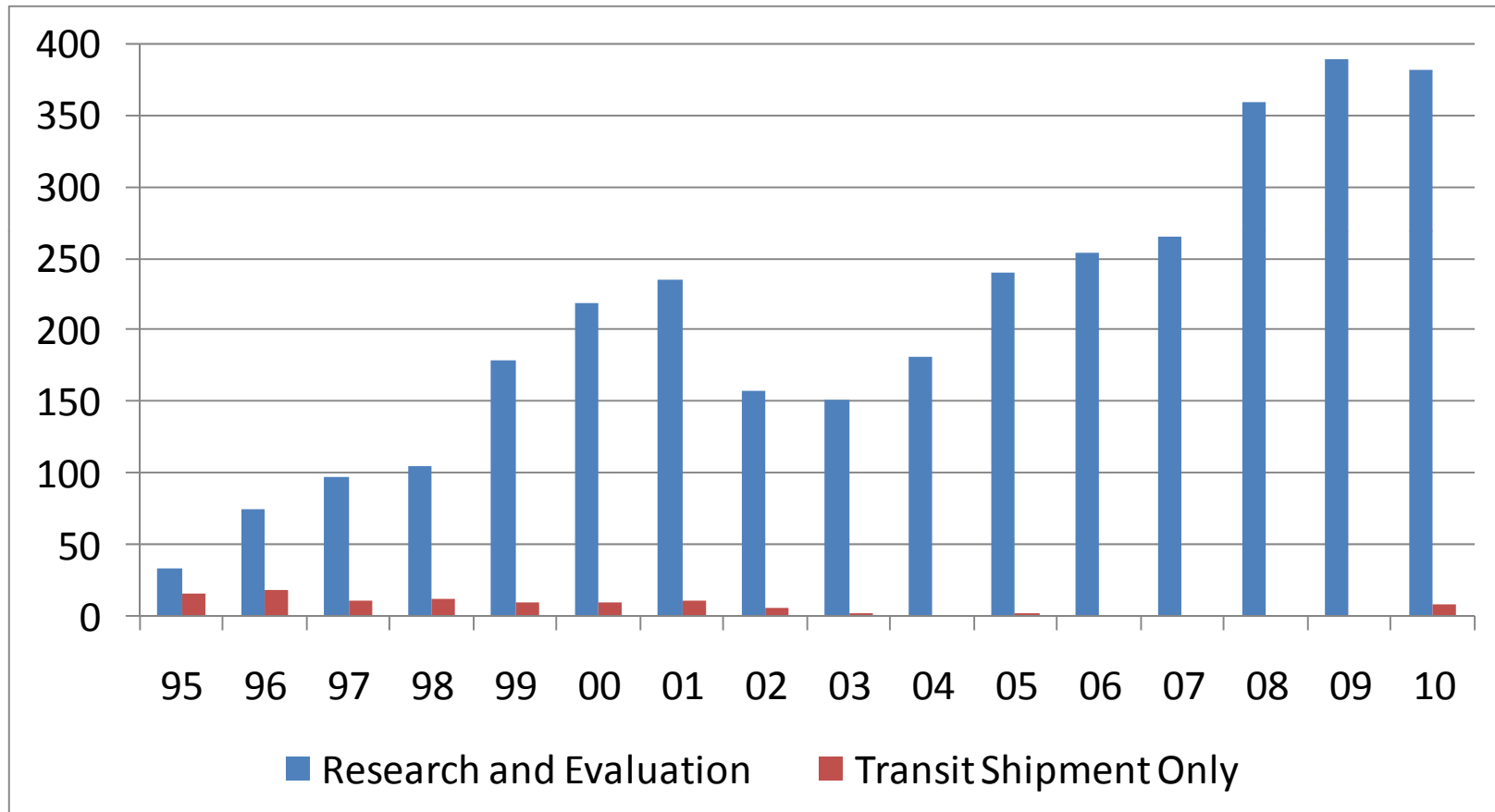
FY2010 Value as of 09/30/10

Permits – FY 2010

No. of Research and Evaluation Permits - 382

No. of Transit Shipment Permits - 8

Veterinary Biologics Permits FY 1995 through FY 2010

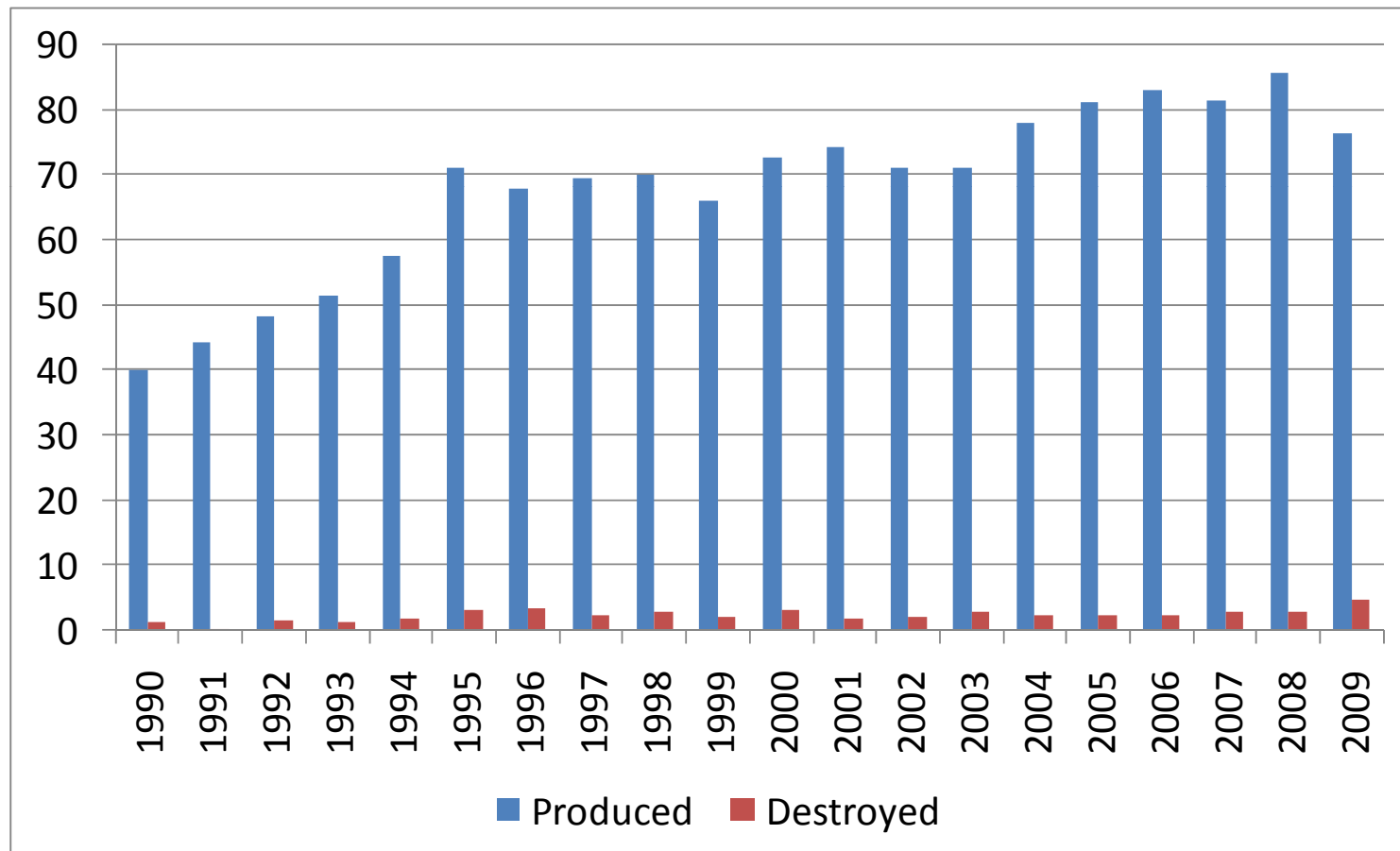


FY2010 Value from 10/01/2009 to 09/30/2010

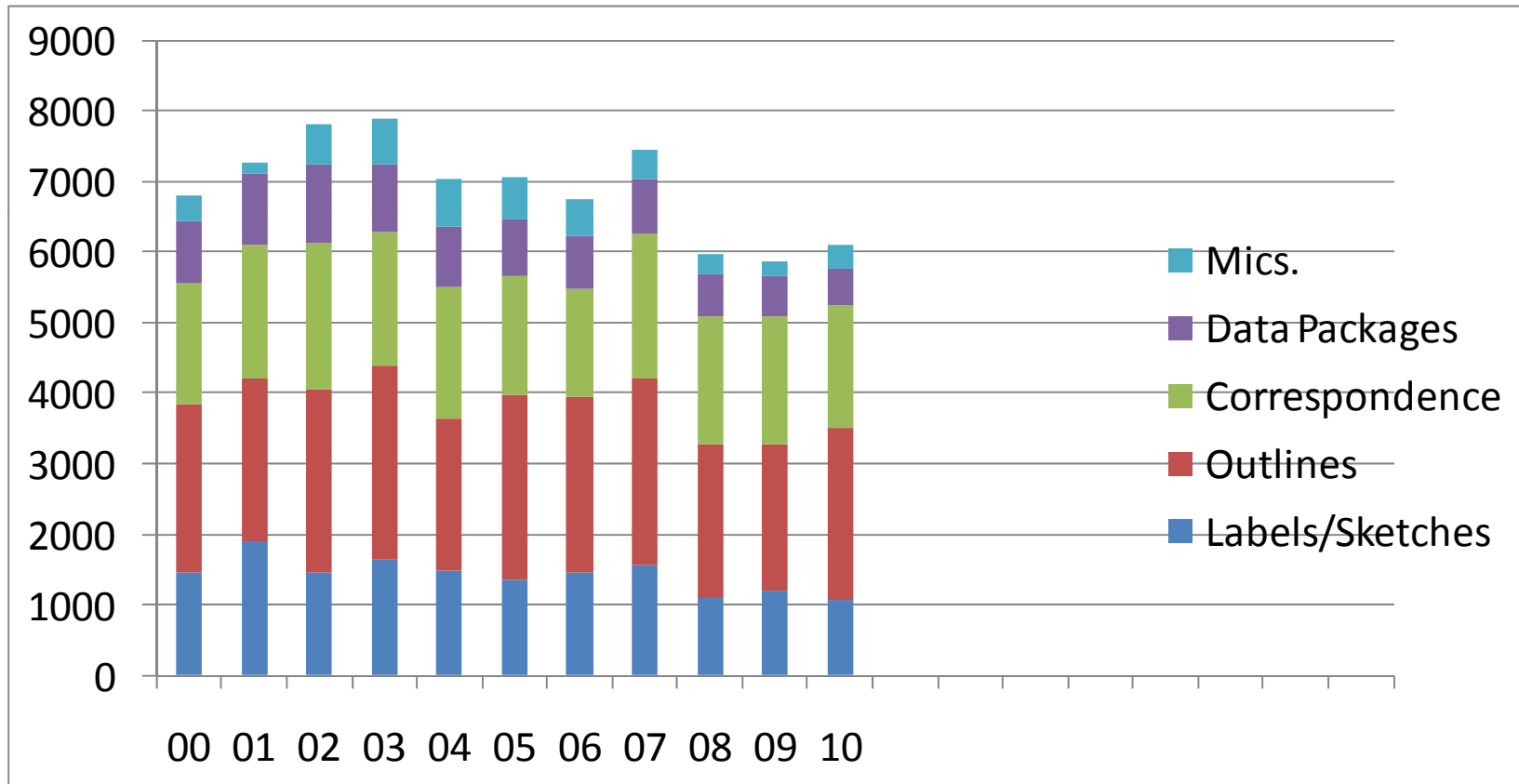
Doses Produced and Destroyed

1990 through 2009 (by calendar year)

Number of Doses - Billion



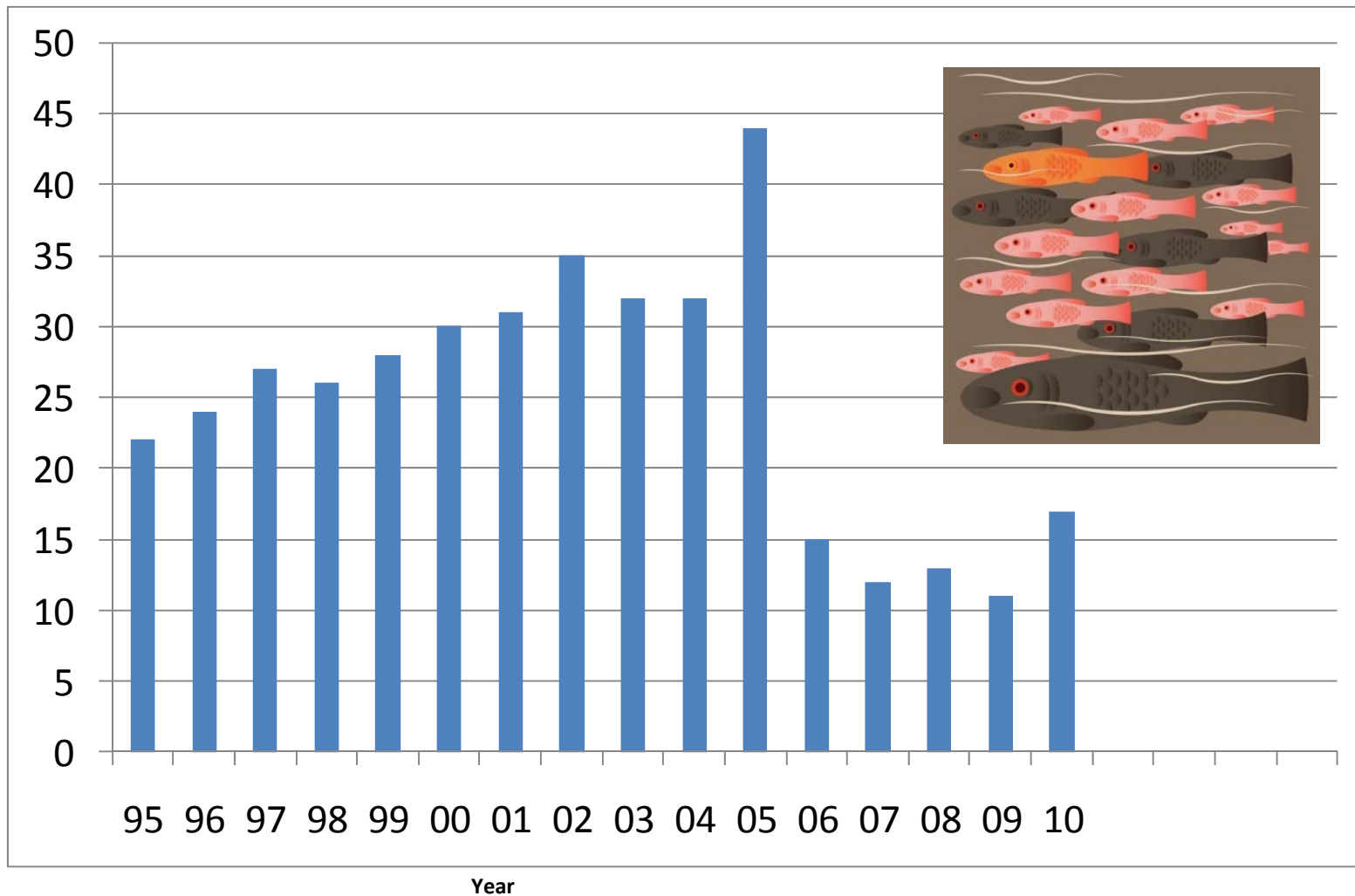
Total Submissions - Compared by Category



FY2010 Values from 10/01/09 - 09/30/10

Aquaculture Products Licensed

Number



FY2010 Value as of 09/30/10 (increase in 2010 due to new report)

Permittees - FY 2010

➤ Asia

- 5 Diagnostics

➤ Canada

- 12 Vaccine/Bacterins
- 2 Antibodies

➤ Europe

- 1 Vaccine/Bacterin
- 13 Diagnostics
- 1 Immunomodulator

➤ Mexico

- 3 Diagnostics

➤ Central/South America

- 1 Immunomodulator

➤ Australia/New Zealand

- 18 Vaccine/Bacterins
- 7 Diagnostics
- 1 Immunomodulator

As of 09/30/2010

Center for Veterinary Biologics

FY 2009 Licensing Summary

	FY06	FY07	FY08	FY09	FY10
Submissions Processed	6646	6656	5663	5635	6014
Product Licenses & Permits	78	63	59	87	88
Total Active Licenses & Permits	2348	2063	2013	1961	1942
Biotechnology Products Licensed	26	19	12	14	11
Unique Products Licensed	11	2	1	2	1
R&E Permits	292	265	359	389	382

Confirmatory and Investigatory Testing

- Testing Numbers for Fiscal Year 2010

– Serials Eligible	18,721	
– Serials (%) Tested	728	(4.31%)
– Serials (%) Unsatisfactory	8	(1.20%)
– Master Cells Tested	10	
– Master Seeds Tested	25	
– Recombinant/ GM MS	7	

Reagents 2010

- Reagents shipped (vials): 3,939
 - Domestic 3,906
 - Foreign 33
- Kit panels/slides 794
- Supplied internal (vials) 25,083
- Reagents developed 13
- Reagents replenished 26

