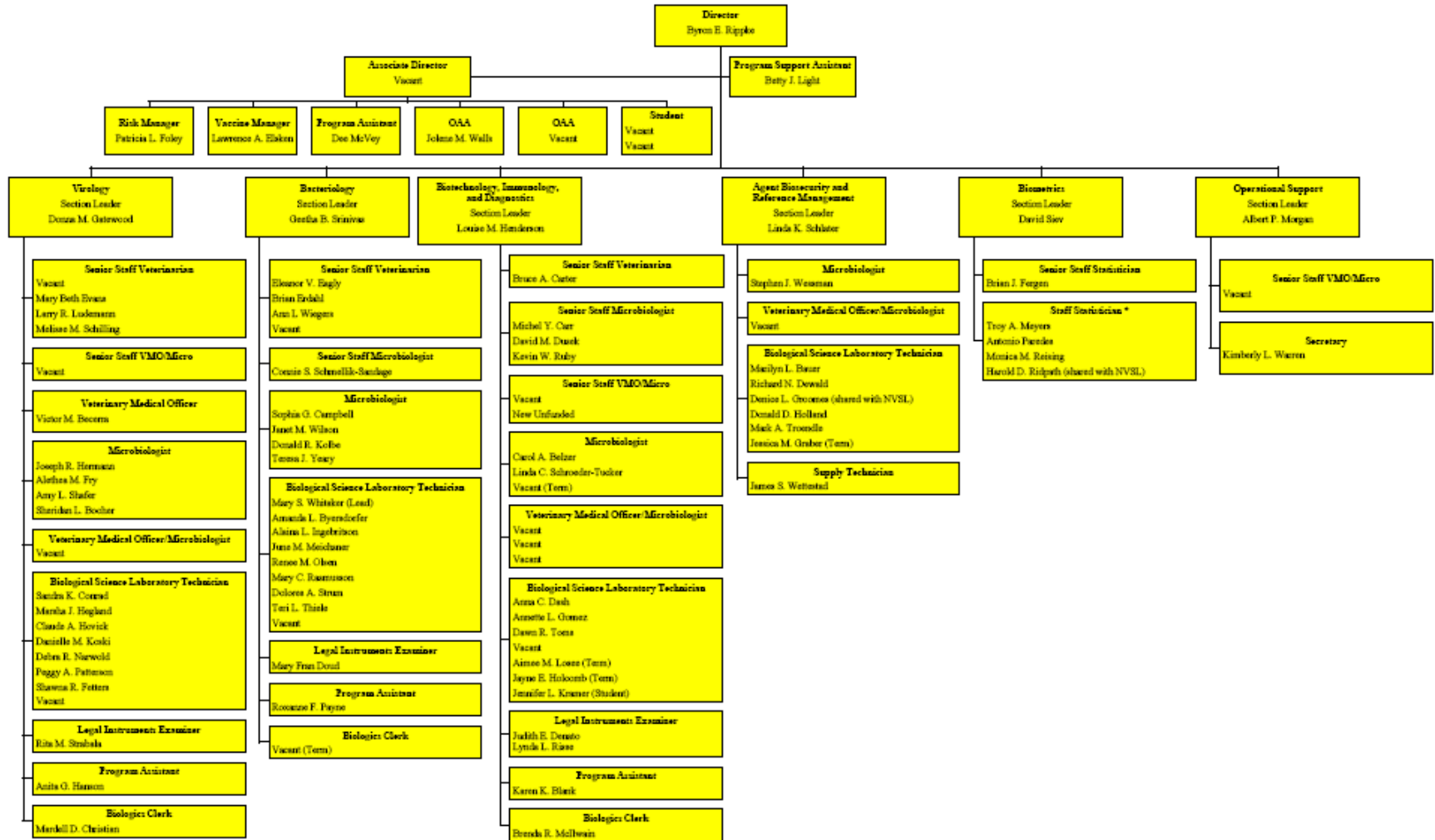


PEL UPDATE

USAHA 2007



Center for Veterinary Biologics Policy, Evaluation, and Licensing



PEL '08 Priority Activities

- Staffing
- Program Documentation
- Application Review
- Laboratory testing
- Program Quality Assurance

Program Documents

- CVB Notices Published in 2007 – 15
- VS Memorandums Published in 2007 – 4
- Documents Posted to the CVB Website for Comment in 2007 - 25

FY 2007

Establishments and Permittees

Issued

3 Establishment Licenses
0 Permittee

Terminated

4 Establishment License
3 Permittee

Total

83 Licensees
18 Permittees

FY 2007 Products

Issued

57 Product Licenses

These include: 3 Unique Product

Terminated

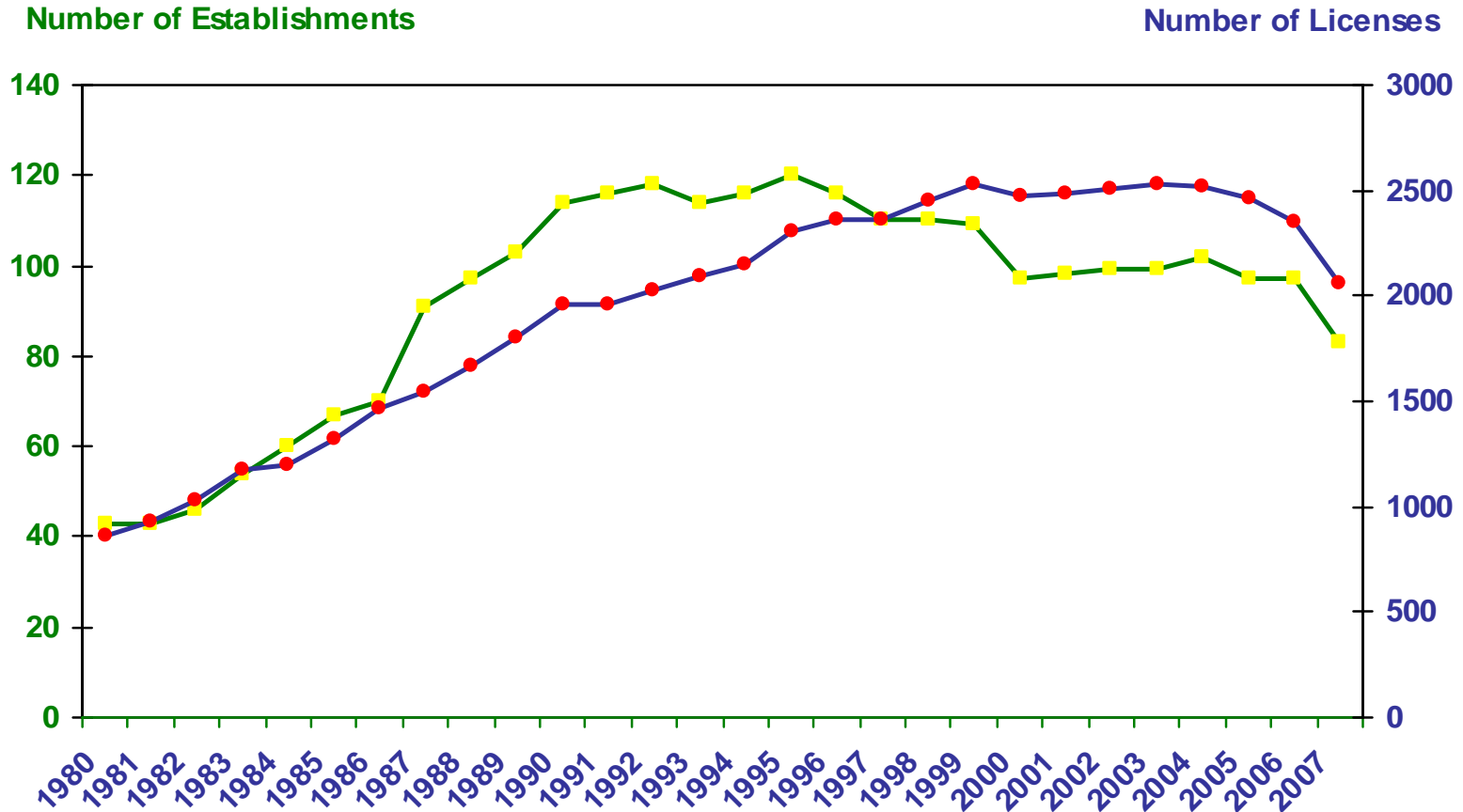
216 Product Licenses

Total

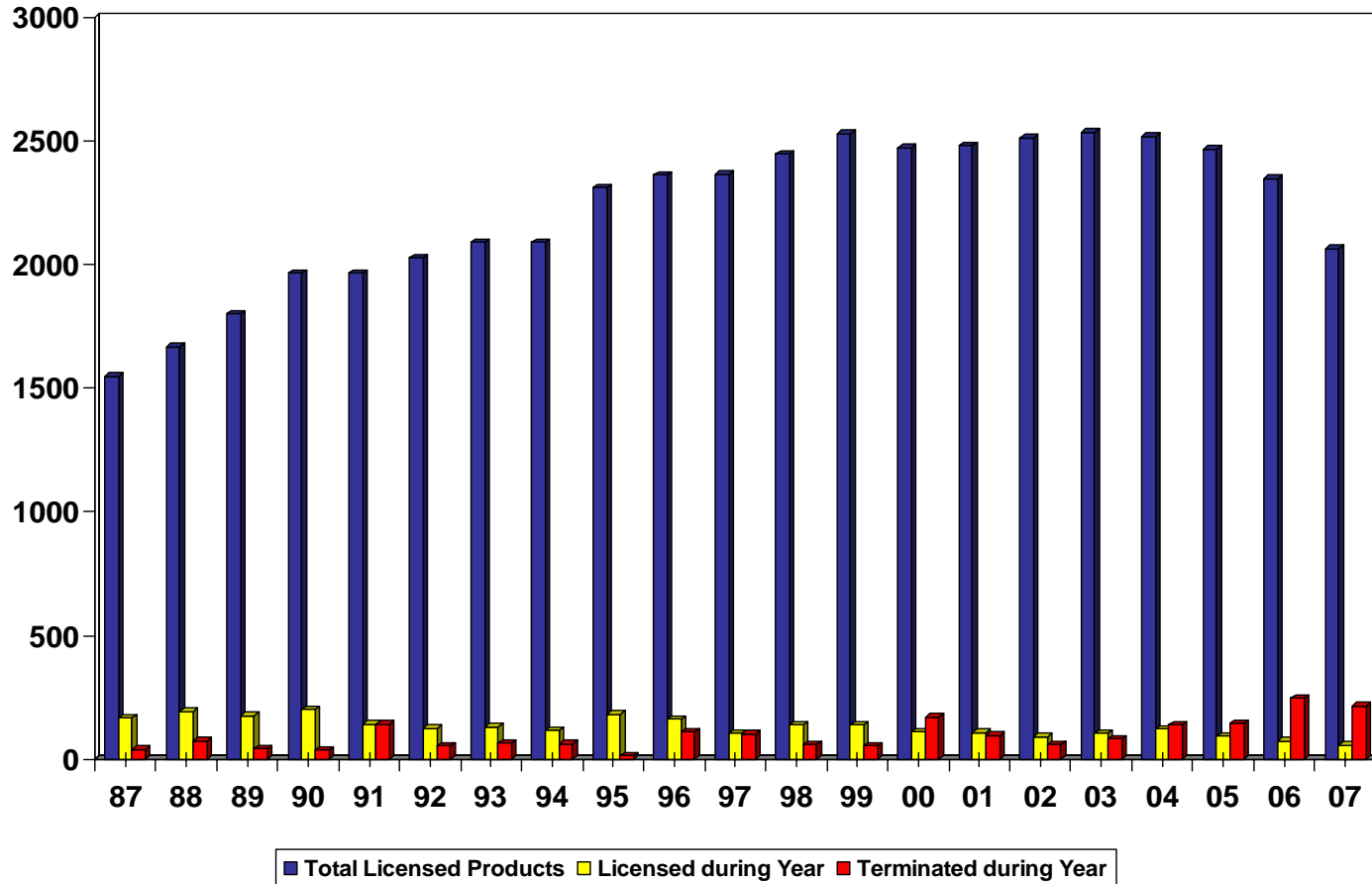
2,063 Active Product Licenses

Veterinary Biologics

Licensed Establishments vs Products

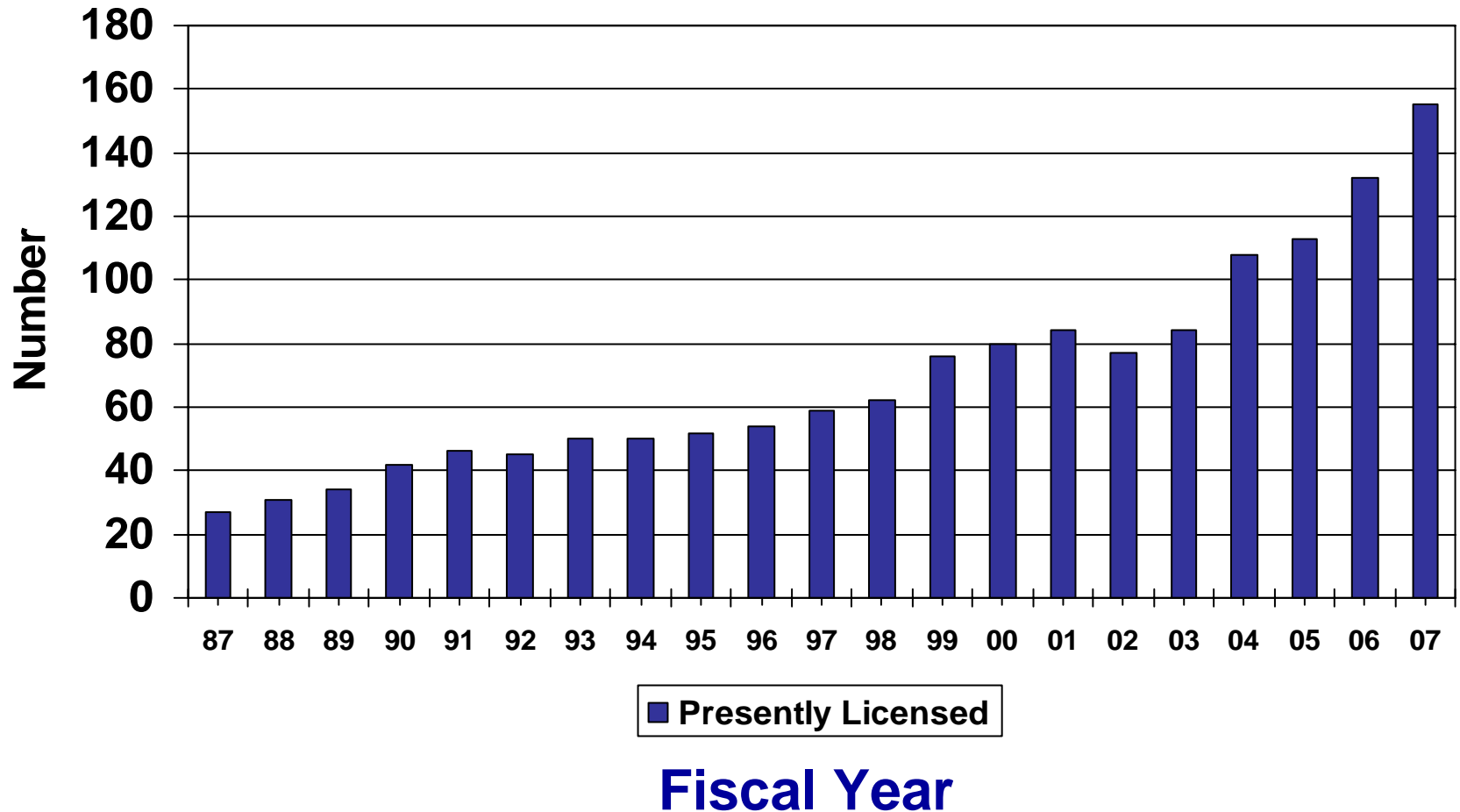


Products Licensed

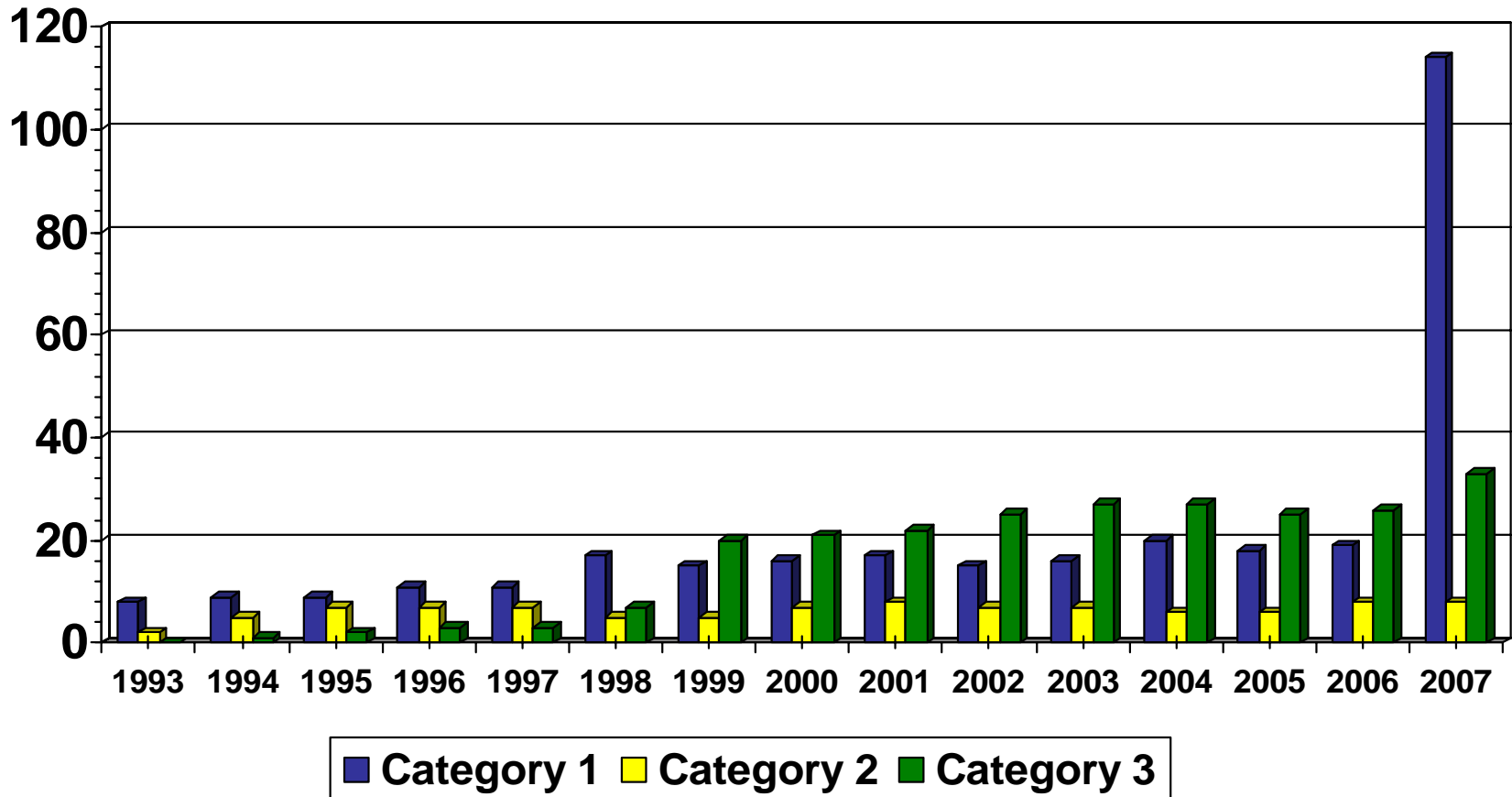


Veterinary Biologics

Biotech Products Licensed



Biotech Products by Category



Note: Figures for 1993 through 2006 do not include Diagnostics

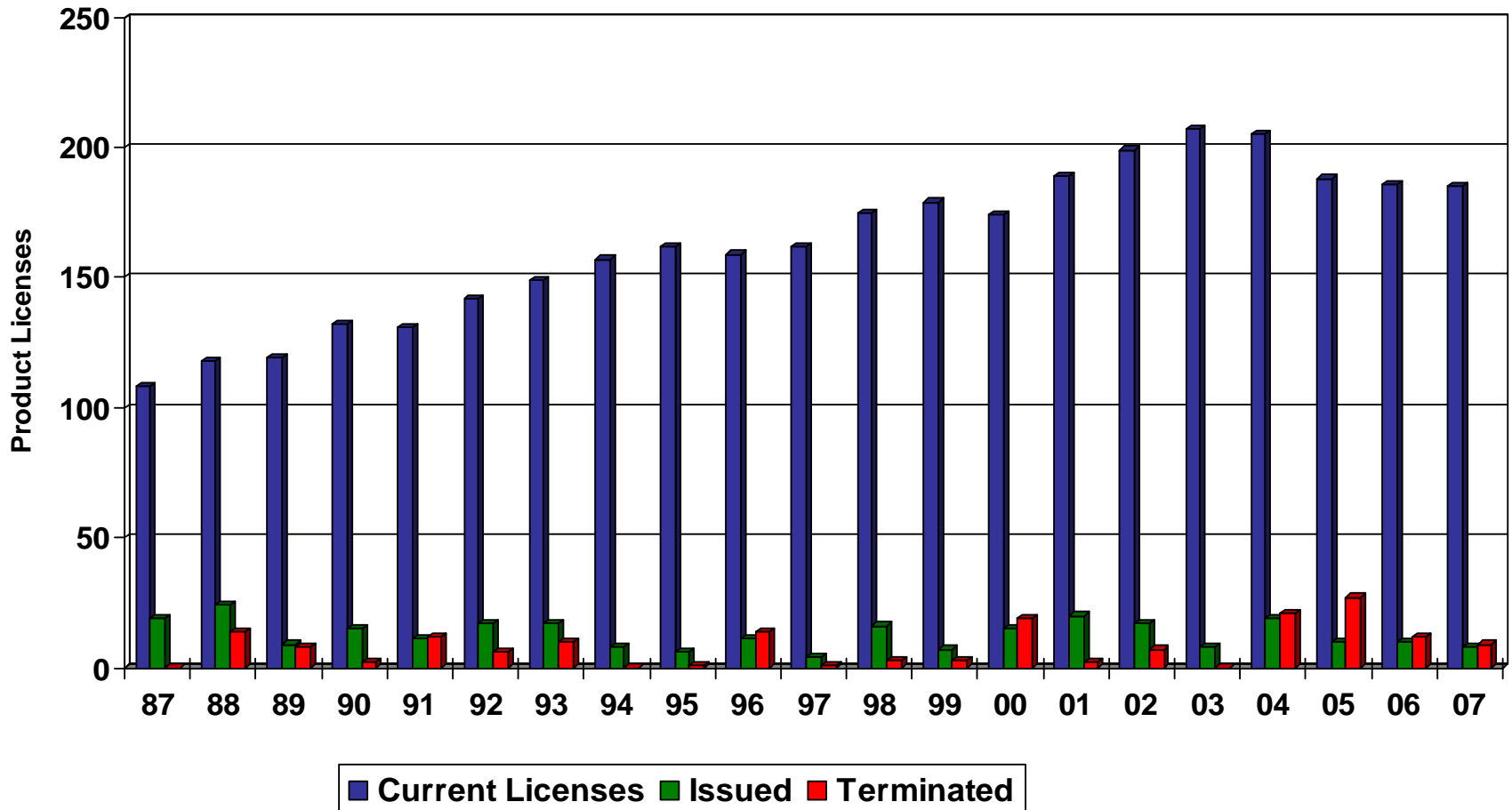
Biotech Products – 2007

All Categories

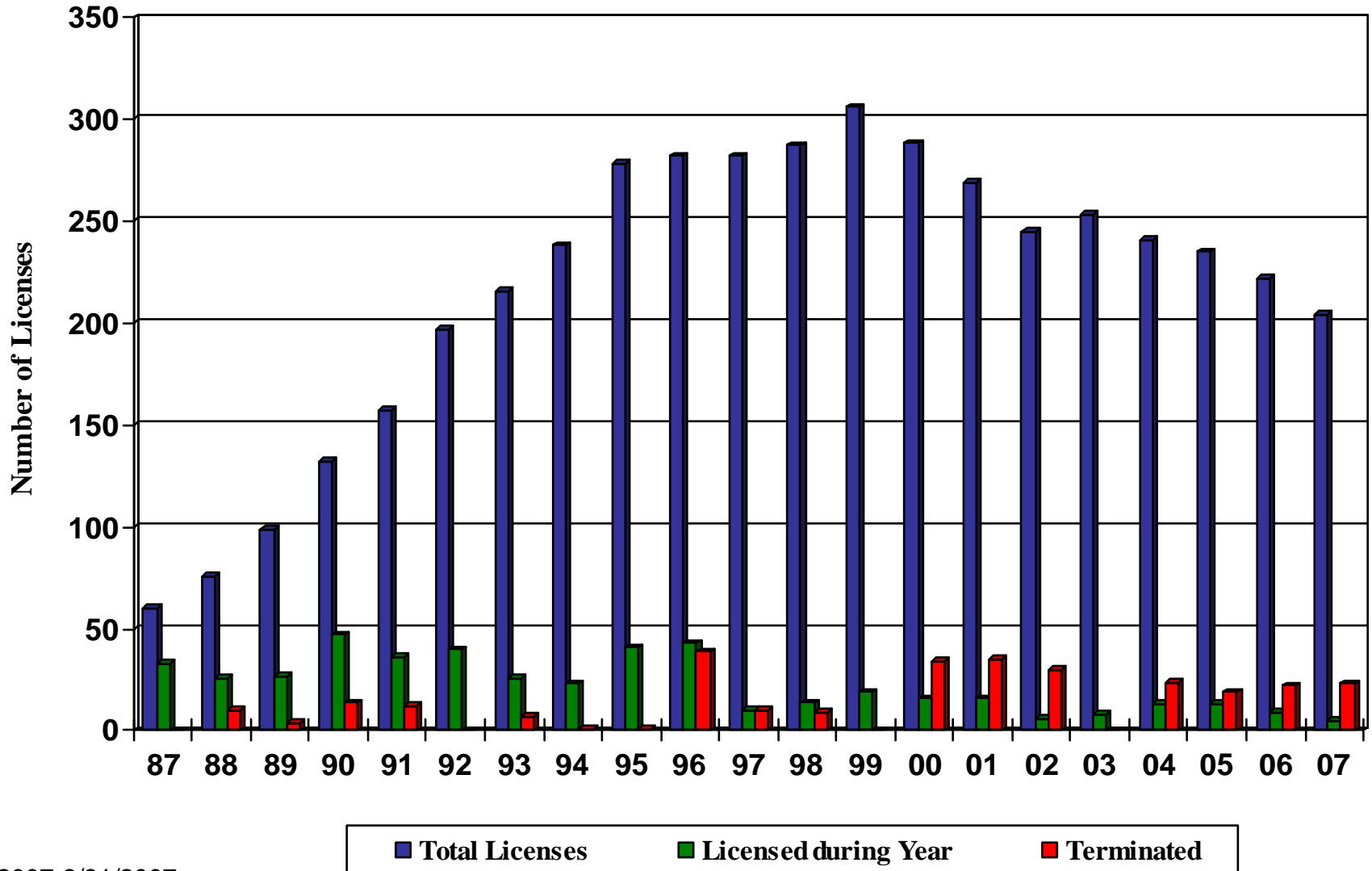
Category 1		Category II	
1-A-1 Non-replicating recombinant antigen(s)-vaccine	16	II Live Gene Deleted	8
1-A-2 Non-replicating recombinant antigen(s)-kits	14	Category III	
1-B-1 Monoclonal antibody-therapeutic/prophylactic use	3		III-A Live Vectored
1-B-2 Monoclonal antibody-used in diagnostic tests	65	III-B-1 Transgenic plant-based-vaccine	1
1-C-1 Synthetic peptide-therapeutic/prophylactic use	2		
1-C-2 Synthetic peptide/oligonucleotide-in diagnostic	10		
1-D-1 Nucleic Acid-Mediated (not Synthetic)-vaccine	2		
1-D-2 Nucleic Acid-Mediated (not Synthetic)-diagnostic	2		

Veterinary Biologics

Number of Diagnostic Product Licenses

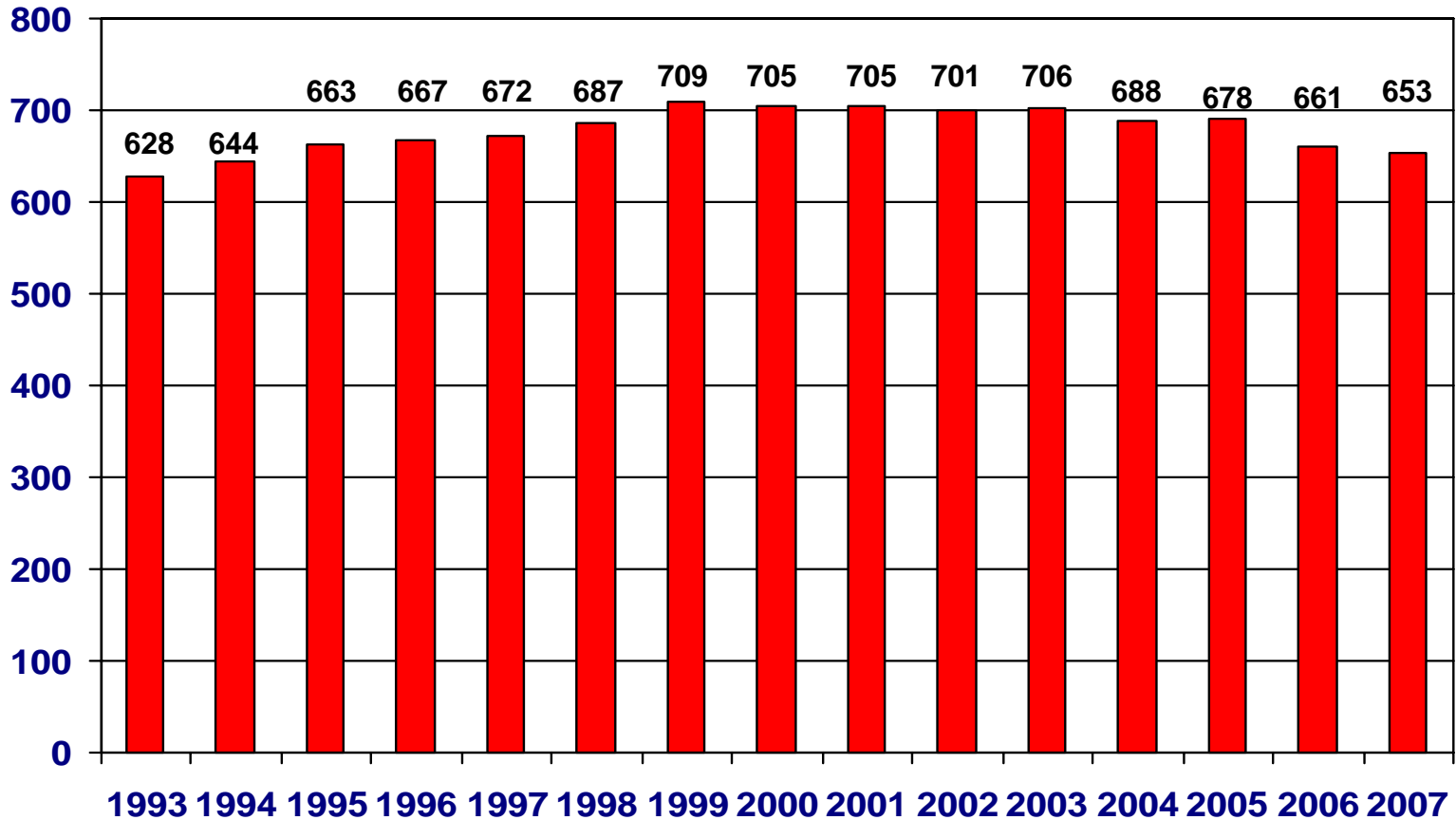


Veterinary Biologics Products Licensed For Further Manufacture



Veterinary Biologics

Unique Products



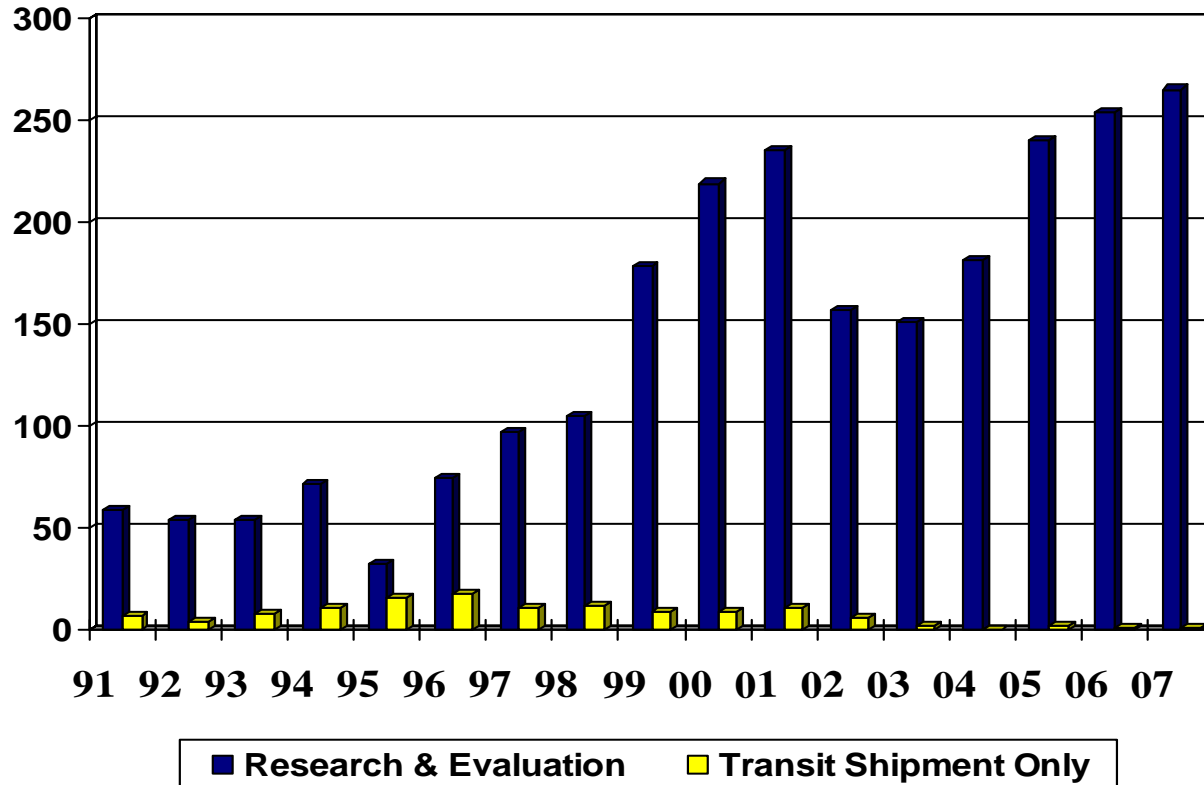
Permits – FY 2007

No. of Research and Evaluation Permits - 265

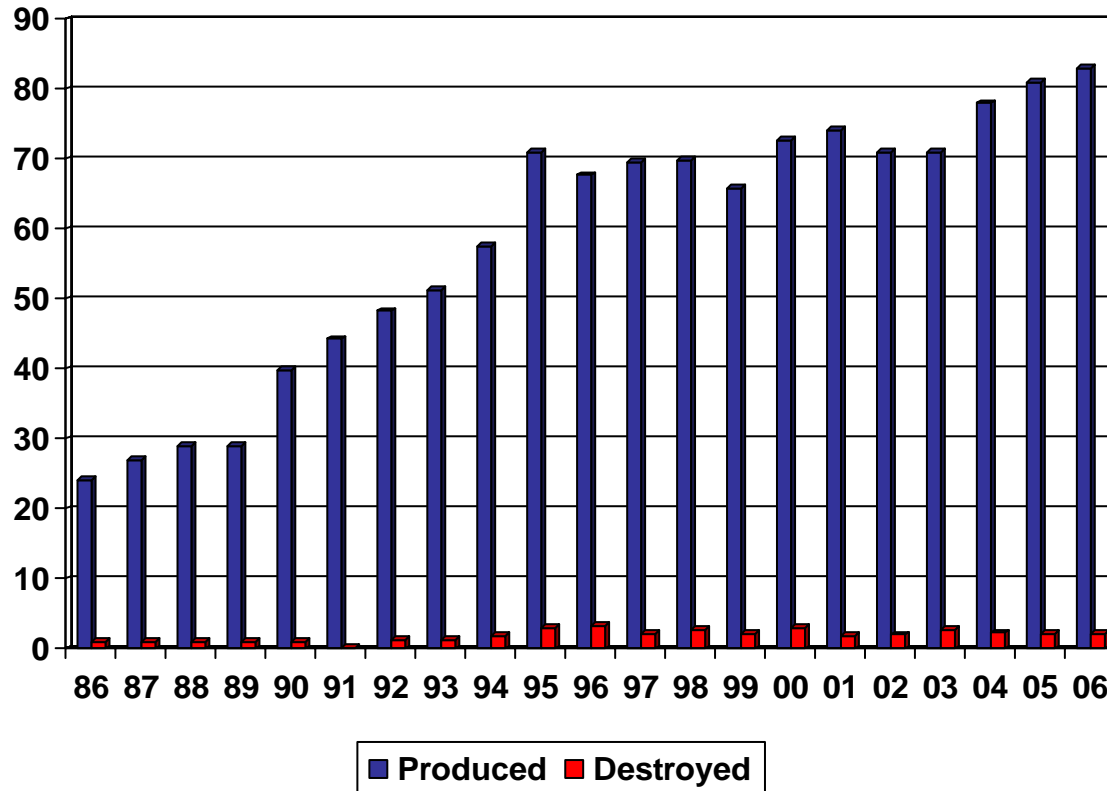
No. of Transit Shipment Permits - 1

Veterinary Biologics Permits

FY 1991 through FY 2007

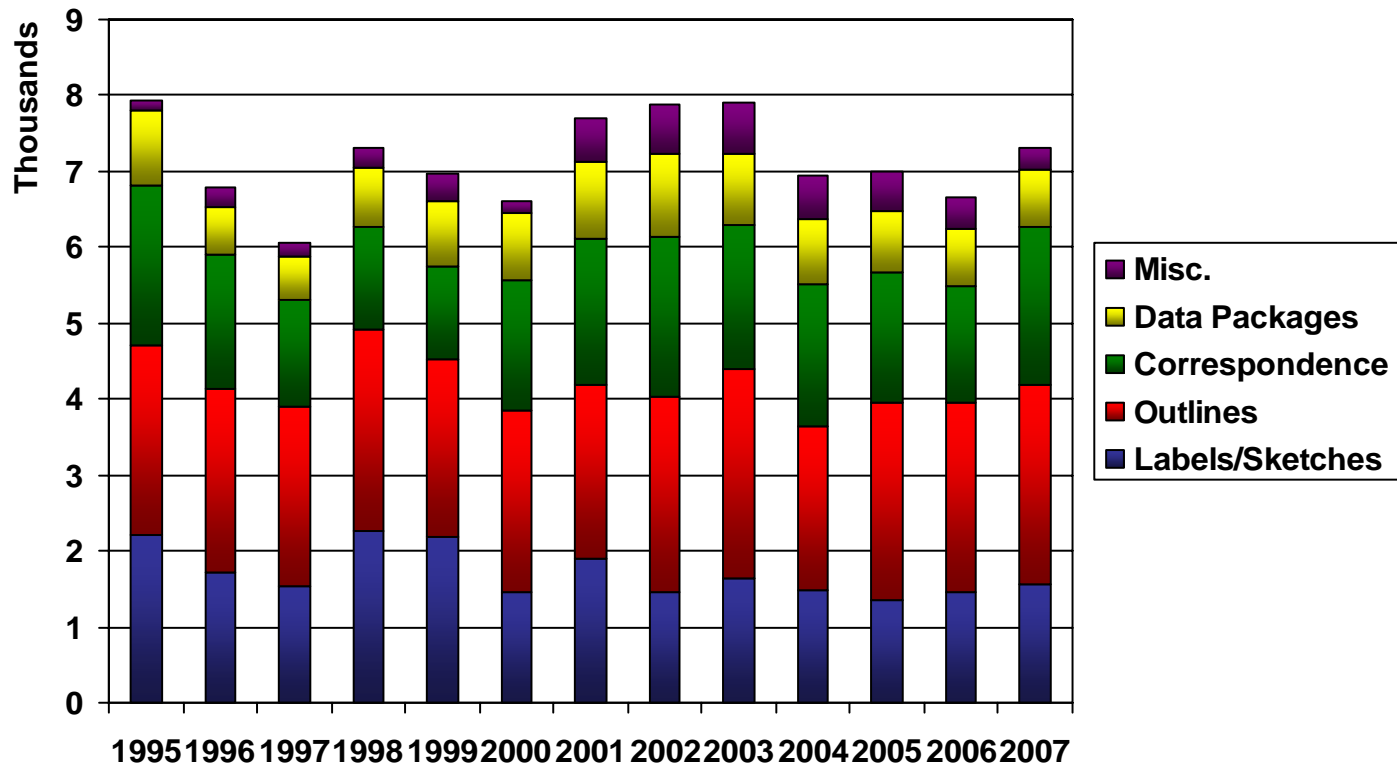


Doses Produced and Destroyed 1986 Through 2006

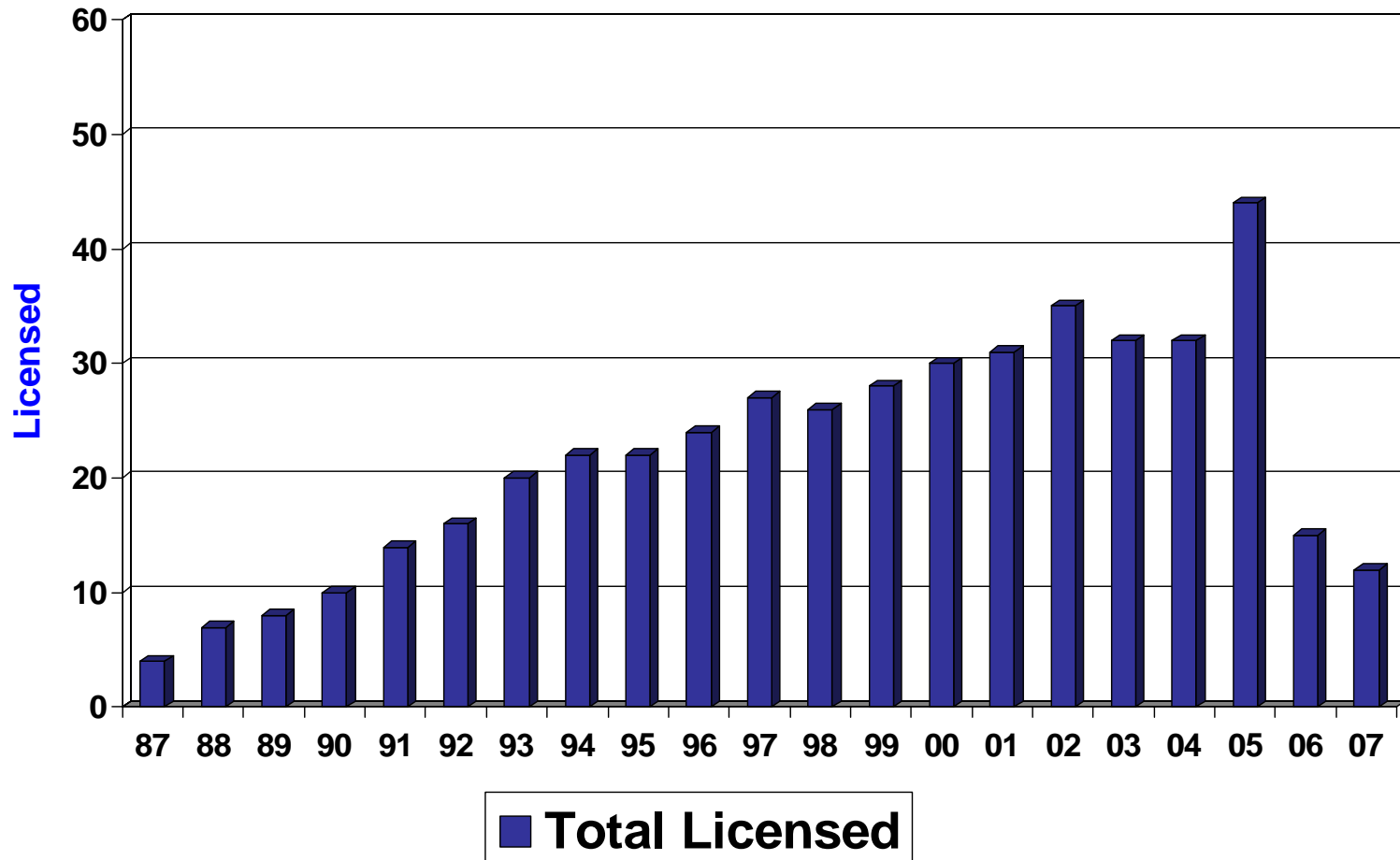
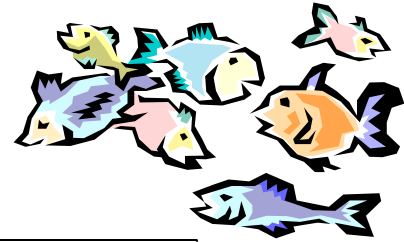
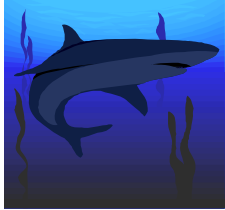


Center for Veterinary Biologics

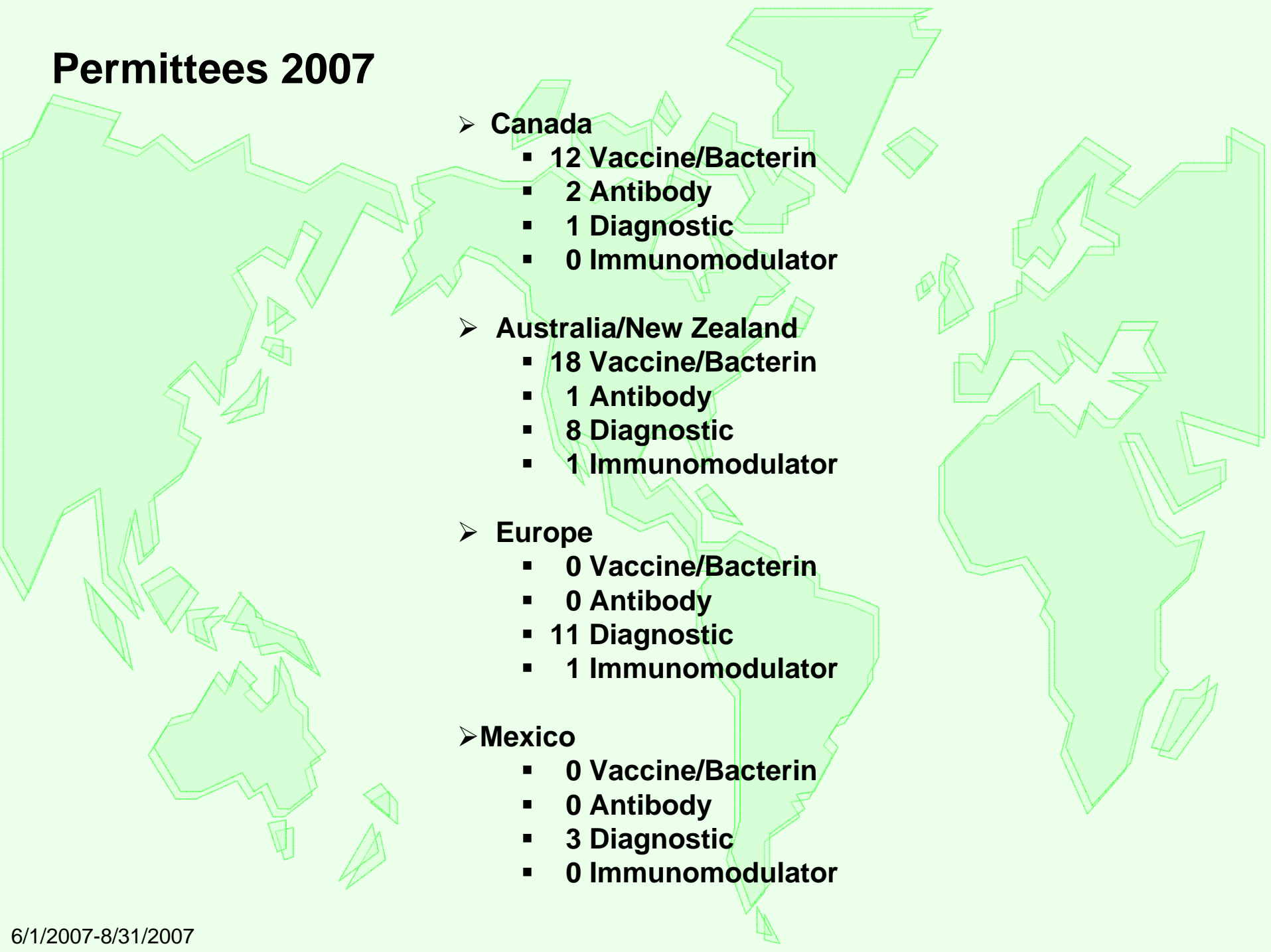
Total Submissions Compared by Category



Veterinary Biologics Aquaculture Products Licensed



Permittees 2007

- 
- **Canada**
 - **12 Vaccine/Bacterin**
 - **2 Antibody**
 - **1 Diagnostic**
 - **0 Immunomodulator**

 - **Australia/New Zealand**
 - **18 Vaccine/Bacterin**
 - **1 Antibody**
 - **8 Diagnostic**
 - **1 Immunomodulator**

 - **Europe**
 - **0 Vaccine/Bacterin**
 - **0 Antibody**
 - **11 Diagnostic**
 - **1 Immunomodulator**

 - **Mexico**
 - **0 Vaccine/Bacterin**
 - **0 Antibody**
 - **3 Diagnostic**
 - **0 Immunomodulator**

Center for Veterinary Biologics

FY 2007 Licensing Summary

	FY05	FY06	FY07
Submissions	6993	6646	6656
Product Licenses & permits Issued	97	78	63
Total Active Licenses & Permits	2465	2348	2081
Biotechnology Products Licensed	25	26	19
Unique Products Licensed	16	11	2
R&E Permits	240	292	265